# Notice seeking clearance for EBOS Medical Devices Australia Pty Ltd to acquire the shares of Pacific Health Supplies TopCo1 Pty Ltd

**PUBLIC VERSION**

18 January 2022

Key: Confidential material in this application has been removed. Its location in the document is denoted by [ ].

# Contents

## SECTION 66 COMMERCE ACT 1986: NOTICE SEEKING CLEARANCE FOR BUSINESS ACQUISITION

18 January 2022

The Registrar
Competition Branch
Commerce Commission, PO Box 2351
Wellington, New Zealand

Pursuant to section 66(1) of the Commerce Act 1986, notice is hereby given seeking clearance of a proposed transaction in which EBOS Medical Devices Australia Pty Ltd (**EBOS**) will acquire 100% of the shares in Pacific Health Supplies TopCo1 Pty Ltd from funds advised by Pacific Equity Partners and other minority holders (the **Proposed Transaction**).

## EXECUTIVE SUMMARY

### The Proposed Transaction

1 By virtue of the Proposed Transaction, EBOS will become the owner of the New Zealand LifeHealthcare (**LHC**) business.

2 EBOS is a subsidiary of EBOS Group Limited (**EBOS Group**). EBOS Group is an Australasian marketer, wholesaler and distributor of healthcare and animal care products. EBOS' Healthcare division includes the Institutional Healthcare business, which (amongst other things) wholesales medical and surgical supplies and medical devices to primary care providers, aged care and hospitals. This division includes Pioneer Medical Limited (**Pioneer**), a New Zealand-based importer and distributor of spine and major joint implants for orthopaedic and neurosurgery applications.

3 LHC is a distributor of medical devices which operates across Australia and New Zealand. LHC is ultimately owned by a diverse range of non-associated investors, including funds managed or advised by Pacific Equity Partners Pty Ltd (**PEP**), an Australian private equity fund manager, and forms part of the Pacific Health Group. Relevantly, LHC distributes complex medical devices in Australia and New Zealand in therapeutic areas including spine, orthopaedics and neurosurgery, and biologics.[1]

4 The Proposed Transaction will result in aggregation in the distribution of complex spinal medical devices, and spinal biologics (allografts or synthetic alternatives), in New Zealand. While the revenue of the Pacific Health Group is approximately [ ], LHC's New Zealand spinal devices business only accounts for [ ], which is less than [ ].

### No lessening of competition

5 The Proposed Transaction is incapable of resulting in a lessening of competition in any market in New Zealand (regardless of how any market is defined) because:

5.1 **existing competition will remain robust**:

(a) The merged entity's market share will be approximately [ ] [ ][2] [ ]. Current competitors include global giant Original Equipment Manufacturers (**OEMs**), such as Medtronic, which supplies (through distributor Scionz) a range of spinal devices and biologics with a current market share of [ ], and NuVasive, which has a current market share in New Zealand of approximately [ ] and is a leader in minimally invasive surgeries,

(b) [

[1] Pacific Health Group acquired Culpan Medical in 2020, which distributes interventional neurovascular devices in partnership with Microvention (an OEM). There is no overlap with these devices with EBOS.

[2] [ ] [ ]

] [

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(c) there are a number of other existing suppliers of spinal devices and spinal biologics active in New Zealand, including global OEMs such as Globus Medical, Zimmer Biomet and Johnson & Johnson, which are well placed to expand, as well as suppliers of other types of medical devices which could readily expand into spinal devices,

5.2 **barriers to entry and expansion are demonstrably low:**

(a) product registration is straightforward as Medsafe does not impose its own requirements. Sales teams can be employed from existing market participants, and OEMs tend to contribute to their training costs,

(b) Pioneer itself only entered the market in 2015 but has already built up to a market share of approximately [ ], and

(c) Alphatec Holdings, Inc (**ATEC**), a US NASDAQ-listed company, has recently entered and will soon offer a broad spinal product range,

5.3 **there is significant countervailing bargaining power**:

(a) PHARMAC exercises a very material constraint. Suppliers must agree prices with PHARMAC and cannot raise them without its consent, and PHARMAC's mandate to maximise value from its finite amount of government funding means that it will not fund relevant products at excessive prices, and

(b) PHARMAC prices also effectively provide a benchmark for the prices that surgeons and funders will agree to in the private sector, and

(c) there are no impediments to surgeons switching suppliers because there are no long-term sales contracts,

5.4 **OEMs can and do bypass distributors and supply directly**. Many OEMs resource their required distribution services in-house. It is not uncommon for OEMs to adopt different strategies for different products within their range, and appoint different distributors for (and within) different countries. As such, distributors like Pioneer and LHC are strongly incentivised not to lower service levels or engage in conduct that would increase the likelihood of OEMs seeking to commence direct supply or replace the distributor. [

], and

5.5 **no vertical, conglomerate or coordinate effects will arise** from the Proposed Transaction, in particular because:

(a) neither Pioneer nor LHC have any ability to leverage or bundle products together, and the Proposed Transaction will not affect that. Neither has

any "must have" devices that could be tied or bundled in a way that would artificially distort or lessen competition (or foreclose a competitor) in any market. Products are necessarily purchased individually based on clinical requirements. The merged entity's product range would not be unique, but rather comparable to other key suppliers. The merged entity will continue to face competitive constraint in respect of every product it supplies, and

(b) the market is characterised by highly specialised products, a high degree of innovation, and firms of different sizes and cost structures.

## PART 1: APPLICANT AND TARGET DETAILS

### Applicant for clearance

6 This notice seeking clearance is given by EBOS. The applicant can be contacted at the details set out below.

Timothy Gargett
Senior Legal Counsel
EBOS Group Limited
[ ]

7 All correspondence and notices in respect of this application for the applicant should be directed in the first instance to:

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E: lucy.cooper@chapmantripp.com / jessica.white@chapmantripp.com

### Other party to the acquisition

8 Contact details for PEP and LHC are set out below.

Matthew Robinson
Managing Director
Pacific Equity Partners
[ ]

Kristine James
Corporate Development Director
LifeHealthcare
[ ]

9 All correspondence and notices in respect of this application for PEP and LHC should be directed in the first instance to:

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Partner / Senior Associate
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E: troy.pilkington@russellmcveagh.com / petra.carey@russellmcveagh.com

## PART 2: TRANSACTION DETAILS

### Overview

10 EBOS entered into a Share Sale Agreement on 9 December 2021 (the **Agreement**) to acquire 100% of the shares in Pacific Health Supplies TopCo1 Pty Ltd and its subsidiaries (together, the **Pacific Health Group**) from funds managed or advised PEP and minority holders (**Proposed Transaction**).[3]

11 The Pacific Health Group, which mainly operates in Australia, comprises interests in three businesses: LHC (100%), Australian Biotechnologies (100%) and Transmedic (51%). By virtue of the Proposed Transaction, EBOS will become the owner of the LifeHealthcare (**LHC**) business.[4]

12 It is the aggregation of the LHC business, and EBOS' subsidiary Pioneer, that gives rise to a limited degree of aggregation in the distribution of spinal medical devices and biologics in New Zealand.

13 A copy of the Agreement is attached as **Appendix 1**. A structure diagram showing the relationship between Pacific Health Supplies TopCo1 Pty Ltd, LHC and their associated entities is attached as **Appendix 2**.

14 Consideration for the shares is approximately AUD 1.17 billion, although LHC's New Zealand spinal devices business represents a very small portion of that amount, with approximately [ ] of this enterprise value attributable to that business.[5]

15 The Proposed Transaction is subject to conditions including Commerce Commission clearance [ ]. The Parties are contractually required to use best endeavours to procure that the Conditions Precedent are satisfied as soon as reasonably possible, and in any event procure satisfaction of the clearance condition by 5pm on 1 June 2022 [ ]. The parties are aiming for completion to occur by the end of March 2022.

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3 For details of the vendors, please refer to the Agreement (in particular Schedule 1) which is attached as **Appendix 1**.

4 [

] [

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5 This represents application of the overall deal ratio to the New Zealand business.

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17 The ACCC is consulting with market participants via a public review process. The public review commenced on 23 December 2021 and the ACCC's provisional decision date is 24 March 2021.[7]

18 Against that background, the Parties would be grateful for the Commission's consideration of this application as soon as possible.

**Commercial rationale**

19 EBOS unilaterally approached PEP in relation to the Proposed Transaction, after identifying Pacific Health Group as offering an attractive complement to its business.

20 The Proposed Transaction is intended to accelerate EBOS' medical devices strategy, being to diversify its range to cover new, higher growth and margin therapy areas. This will enhance the depth and breadth of EBOS' product and channel offerings and assist it to grow and attract new OEM relationships. The Proposed Transaction will also enable EBOS to establish an Asian base for expansion into that region, further expand and diversify EBOS' earnings and, through an equity raising recently completed to partially fund the proposed acquisition, enhance EBOS' share trading liquidity.

21 [

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[7] For further details, please see https://www.accc.gov.au/public-registers/mergers-registers/public-informal-merger-reviews/ebos-group-limited-pacific-health-supplies-topco1-pty-limited.

## PART 3: BACKGROUND TO THE RELEVANT PRODUCTS

### Introduction to medical devices

22 Medical devices encompass a broad range of products and include all items used in medical diagnoses, surgery and treatment. Common broad therapeutic areas for suppliers of medical devices include spine, orthopaedics, general surgery, plastics and reconstruction, robotics, neurosurgery, medical capital and consumables, and interventional neurovascular.[8]

23 Within a therapeutic area, medical devices have very specific applications (for example, a spinal disc implant cannot be used in a hip replacement). Even within a particular therapeutic area, high-end medical devices have very specific applications (for example, in spine, a cervical disc replacement would not be used for a lumbar disc replacement).

24 This application is only concerned with overlap in spinal medical devices and spinal biologics.

### Spinal medical devices

25 Spinal medical devices are specifically designed for use in spine surgery. Examples of key highly specialised spinal devices are pedicle screws, bone screws, cages that can hold bone grafts and act as a space holder between vertebrae, and disc replacements.

26 Spinal medical devices supplied by both of the Parties are in **Appendix 3.**

### Spinal biologics

27 Biologics are often used with spinal medical devices to stimulate and promote healing, bone growth or fusion. Biologics are therefore typically purchased at the same time, although not as a bundle and not necessarily from the same supplier. Surgeons can and do mix and match products from different suppliers and/or manufacturers.

28 Spinal biologics include:

28.1 allografts,[9] which are products made from donated human tissue,

28.2 demineralised bone and demineralised bone matrix (**DMB**) products,[10] and

28.3 synthetic alternatives to the above.

29 Biologics supplied by both of the Parties are included in **Appendix 3.**

### Suppliers of medical devices and biologics

30 There are two main categories of industry participants:

30.1 OEMs, which supply directly to customers in local markets, and

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[8] See, for example, this overview of the therapeutic areas in which LHC is active in Australia: https://www.lifehealthcare.com.au/what-we-do/

[9] Allografts are different to "autografts", in which a patient's own tissue is used.

[10] DMBs are effectively allograft bones that have been decalcified by acid extraction.

30.2 distributors, which work on behalf of OEMs to supply customers.

***OEMs***

31 In New Zealand the wider medical devices sector is characterised by a number of OEMs, the majority of which are foreign multinational corporations.

32 Some OEMs (such as NuVasive, Globus Medical and Zimmer Biomet) choose to supply directly to customers for all or part of their product range, while others, such as Stryker[11] and RTI Surgical choose to engage a local distributor such as LHC or Pioneer. Pioneer estimates that there are approximately 200 medical device suppliers in New Zealand of varying size and specialties. The Medical Technology Association of New Zealand (**MTANZ**) website alone lists more than 80 importers of medical devices.[12] Both OEMs and distributors of medical devices tend to focus on one or more broad therapeutic areas.

33 Globally, the largest OEMs involved in spinal medical devices are:[13]

33.1 Medtronic,

33.2 Johnson & Johnson,

33.3 NuVasive,

33.4 Stryker,

33.5 Globus Medical,[14]

33.6 Zimmer Biomet,

33.7 RTI Surgical,

33.8 Orthofix,

33.9 SeaSpine, and

33.10 ATEC.

34 Contact details for the parties' competitors (suppliers of spinal medical devices and associated biologics) currently active in New Zealand are set out at **Appendix 4**.

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[11] It is also not uncommon for OEMs to adopt different strategies for different products within their ranges, and appoint different distributors for (and within) different territories. For example, [

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[12] Based on membership of the Medical Technology Association of New Zealand that are listed on that website as being "medical device importers". See Industry Directory - MTANZ - Medical Technology Association of New Zealand.

[13] This is a 2019 assessment from Becker's Spine Review, a specialist industry publication. See https://www.beckersspine.com/.

[14] There are recent reports of an upcoming takeover attempt of NuVasive by Globus Medical: see https://www.nasdaq.com/articles/nuvasive-nuva-up-on-rumors-of-takeover-by-globus-medical, https://www.beckersspine.com/orthopedic-a-spine-device-a-implant-news/item/53065-nuvasive-stock-spikes-after-news-of-possible-takeover-4-notes.html?origin=SpineE&utm_source=SpineE&utm_medium=email&utm_content=newsletter&oly_enc_id=4279F3197745J5A.

***Distributors***

35 Distributors do not themselves own any intellectual property in devices, but offer a range of services to OEMs, including marketing, support for local product registration and access to local customer relationships. Distributors also offer clinical education support to surgeon-customers. OEMs are capable of providing these services themselves, but may choose to appoint a distributor instead.

36 The work of distributors is carried out by sales staff with the necessary clinical knowledge and expertise to educate surgeon-customers about the use of devices in a particular therapeutic area. Given the investment required to train staff in particular devices, distribution relationships are often exclusive, although OEMs may engage different distributors for products in different therapeutic areas.

**Regulatory requirements**

37 Devices must be registered on the Web Assisted Notification of Devices (**WAND**) Medsafe Database before being distributed in New Zealand. This is also one of the requirements of PHARMAC's terms and conditions (see further below).[15]

38 However, Medsafe does not impose substantive requirements for approval.[16] In practice, suppliers rely on regulatory approvals from jurisdictions perceived as trustworthy, such as the United States of America or Australia, to persuade surgeons of the credentials of devices they offer.

**Surgeon-customers**

39 The decision-maker as to which device and which biologics products to procure for a particular surgery is typically the surgeon. This is the case in both the public and private sectors. In the Parties' experience, the surgeon will consult the patient about the selection of products, but the surgeon's advice is usually accepted.

40 Spinal surgeons use a range of devices as part of their work. It is rare for a surgeon to use only one supplier's devices in all the procedures they perform. Surgeons frequently use products from different OEMs, even within the same procedure, where they see clinical advantages. This may be because their preferred supplier (be it an OEM or a distributor) does not supply the device required by the surgeon, or the surgeon considers that another supplier's device is more innovative or achieves better patient outcomes. Surgeons tend to consult with OEM and/or distributors' sales staff about their requirements before choosing a device.

**Funding**

41 The cost of spinal medical devices and biologics is borne by District Health Boards (**DHBs**), ACC, health insurers or patients. Where a surgery is publicly funded, the price for the device is agreed with PHARMAC.

42 From a practical perspective, [

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[15] See standard terms and conditions (https://pharmac.govt.nz/assets/Attachment-2-standard-terms.pdf), clause 7.1(b). [

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[16] See https://www.medsafe.govt.nz/regulatory/DevicesNew/3-2Explanation.asp.

].

***PHARMAC***

43 For public patients, PHARMAC[17] lists registered devices, and agrees the prices at which they will be made available to DHBs. As such, for public surgeries, price competition among suppliers takes place at the time of registration and day-to-day competition takes place for surgeon-customers on non-price terms (such as technology and service).

44 While PHARMAC does not currently limit the number of devices that may be registered, suppliers must agree pricing with PHARMAC and agree to PHARMAC's terms and conditions, which leave very little scope for negotiation.[18]

45 Also attached as **Appendix 6** is a copy of a request for proposal (**RFP**) issued by PHARMAC, which sets out the process by which Pioneer's products were registered in 2016. The RFP records that PHARMAC has been asked to take on a greater role in medical devices, specifically in relation to negotiating national contracts to centralise and streamline supply arrangements. It states that, in deciding which products to fund, it will take into account:

45.1 product specifications,

45.2 price,

45.3 ability to provide appropriate level of clinical support, including training and education, and

45.4 ability to provide DHB usage data.

46 The RFP states that "[e]ach proposal will be evaluated on the basis that the price offered, the expenditure entailed, and any other terms included in the proposal, are the best that the supplier is able to offer. If you do not put forward your best terms you risk having your proposal excluded at the evaluation stage."[19]

47 Because of PHARMAC's statutory mandate to, in effect, secure pharmaceuticals (including medical devices) for the best health outcomes within funding constraints, it generally puts significant downward pressure on prices to maximise the use of its taxpayer funding. Its website records that it has been very successful at negotiating costs down, enabling the funding of new products.[20]

48 Through these processes, PHARMAC is capable of materially constraining suppliers. For example, suppliers cannot increase prices during the term of the agreement

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17 As the Commission will be aware, PHARMAC's objective is to secure for eligible people in need of pharmaceuticals, the best health outcomes that are reasonably achievable from pharmaceutical treatment and from within funding constraints. See How Pharmac works - Pharmac | New Zealand Government.

18 Attached as **Appendix 5** is a copy of the terms and conditions on which Pioneer has agreed to supply the products it distributes to DHBs [ ], and the standard template terms and conditions can be found here: https://pharmac.govt.nz/assets/Attachment-2-standard-terms.pdf.

19 See **Appendix 6**, paragraph 2(e).

20 See How Pharmac works - Pharmac | New Zealand Government. Note that the definition of pharmaceutical in the New Zealand Public Health and Disability Act 2000 includes a therapeutic medical device (section 6).

without PHARMAC's agreement. [

] [

] This constraint would be unaffected by the Proposed Transaction.

49 On the basis of PHARMAC's decision to list certain products and the resulting terms of any contract between PHARMAC and the supplier, DHB hospitals are able to place purchase orders with the supplier for the relevant products (either directly or through a logistics/procurement provider) on PHARMAC terms.[21] As above, in practice, these decisions are made by surgeons. The supplier may charge a DHB no more than the price agreed with PHARMAC.

50 PHARMAC may choose to run another RFP at any time. In the meantime, outside of the RFP process, it is possible for suppliers to negotiate with PHARMAC to have devices funded as follows:[22]

50.1 suppliers can upgrade relevant medical devices. If the upgraded device continues to conform to the same product specification, PHARMAC's terms provide that consent to list the new device in place of the old one will not be unreasonably withheld, and

50.2 PHARMAC's terms envisage that, as clinical practice evolves or new technology becomes available, clinical practice may change, resulting in DHB hospitals ceasing to use certain devices or preferring an upgraded form. If that occurs, PHARMAC can delist any relevant device from the funded schedule and may list a new device in its place. Suppliers are required to keep PHARMAC informed of any international trends and studies that are relevant to or relate in any way to any devices.

51 The current list of spinal devices that are funded by PHARMAC (and the supplier of each one) is attached as **Appendix 7**.

52 As the Commission is aware, PHARMAC has a number of additional options available to it to help drive down the price of products it lists, which it could deploy in the event any supplier sought to exercise market power. Furthermore, [

] In a 2019 consultation about its management of medical devices, PHARMAC noted that over time it would identify opportunities to achieve greater value for money, "…for example, by leveraging competition to achieve the same health outcomes at less cost. This could be done by offering exclusive benefits

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[21] See clauses 3 and 4 of PHARMAC's standard terms [ ] – see n 18 above.

[22] See clause 13 of PHARMAC's standard terms [ ] – see n 18 above.

to a particular supplier or subset of suppliers of products which all deliver similar health outcomes, in exchange for more competitive terms."[23]

53 PHARMAC has also proposed that it undertake more proactive "list management" in future. This would involve ensuring that the national medical devices list remains current and reliable, and PHARMAC has noted that the effect of list maintenance decisions could be that products may be delisted. One example given of when this may occur is "…if PHARMAC and a supplier had not reached agreement on a desired change".[24]

54 In summary, PHARMAC exercises material bargaining power and has a number of additional tools at its disposal to prevent any attempted use of market power.

***DHBs***

55 Surgical departments generally look to the clinical head of the department i.e. a surgeon, to choose suppliers and products. So, as above, it is generally the surgeons who set the key criteria for which devices to acquire based on the price and non-price terms that are offered. The devices are available at the prices agreed with PHARMAC.

***ACC, health insurers and patients***

56 ACC and health insurers may fund a device and biologics as part of the surgical procedure, depending on the application of ACC's funding criteria or the particular health insurance policy terms. Patients may self-fund to the extent that devices and biologics are not covered by a health insurer or ACC. Self-funding of medical devices by patients is estimated by Pioneer to only occur in approximately [ ] of all cases.

57 For such non-DHB funded patients, suppliers agree on price with, or via, surgeons. The surgeon, or patient, deals with the funder rather than the supplier doing so. In practice, as discussed in more detail below, surgeons generally work across the public and private sectors and therefore they (and their patients, ACC and health insurers) have visibility of PHARMAC pricing. Surgeons and funders therefore tend to insist on purchasing devices at, or with a clear link to, PHARMAC prices (see paragraph 112).

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[23] See Managing fairer access to hospital medical devices - consultation 2019 (pharmac.govt.nz), page 21.

[24] See Managing fairer access to hospital medical devices - consultation 2019 (pharmac.govt.nz), page 21.

## PART 4: THE PARTIES

### EBOS

58 EBOS Group Limited (the **EBOS Group**), of which EBOS Medical Devices Australia Pty is a part, is an Australasian marketer, wholesaler and distributor of healthcare, medical and pharmaceutical products and animal care products.[25] In the financial year ended 30 June 2021, it generated more than AUD 9 billion in revenue annually, and its total revenue in New Zealand for FY2021 was AUD 1.8 billion, across all its businesses.[26] It is publicly listed on the ASX and NZX.

59 The EBOS Group has two key business divisions: Healthcare and Animal Care. The Healthcare division is separated into three areas, being Institutional Healthcare (the division relevant to the Proposed Transaction), Community Pharmacy and Contract Logistics. EBOS operates through all three divisions in New Zealand. Broadly speaking:

59.1 the Institutional Healthcare division wholesales pharmaceuticals, over-the-counter medicines, medical and surgical supplies (such as medical consumables) and medical devices to primary care providers, aged care and hospitals,

59.2 the Community Pharmacy division supplies pharmaceuticals, over-the-counter medicines and other healthcare-related products, and provides logistical services to pharmacies, as well as supplying various consumer health products to pharmacies and other retailers, and

59.3 the Contract Logistics division provides warehousing, distribution, clinical trial management, product registration and logistics services to manufacturers.

60 The Animal Care division in New Zealand wholesales pet food, treats and other pet-related products, as well as holding a 50% interest in in Animates, a network of specialty pet retail outlets and veterinary clinics in New Zealand (the remaining 50% is owned by Greencross Limited).

61 The EBOS Group' Institutional Healthcare division includes a number of medical device distribution businesses servicing a range of therapeutic areas, being:

61.1 LMT Surgical, acquired in 2019, which supplies products and services for orthopaedic (extremities), spine and neurosurgery (but not in New Zealand) and sports medicine procedures, as well as products for multi-surgical specialties across Australia and New Zealand,[27]

61.2 Cryomed Aesthetics, acquired in 2020, which is a provider of aesthetic healthcare devices, medical-grade cosmeceuticals and injectables across Australia and New Zealand,

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[25] For an overview of EBOS' business, see https://www.ebosgroup.com/.

[26] EBOS 2021 Annual Report, p 36 (available online here).

[27] [

61.3 MD Solutions, acquired in 2021, which distributes a range of medical devices and consumables for interventional oncology, urology and gynaecology, pathology and diagnostics, gastroenterology, and ear, nose and throat procedures, as well as offering a service for repair of endoscopes, in Australia and New Zealand, and

61.4 Pioneer, which EBOS acquired in August 2021. Pioneer is a New Zealand-based importer and distributor of spine and major joint implants associated with surgical technologies for orthopaedic and neurosurgery applications.[28]

62 The EBOS Group's only overlap with LHC in New Zealand is through Pioneer.[29]

63 Pioneer's website is at: www.pioneermed.co.nz.

64 EBOS is a member of **MTANZ**.[30] EBOS's contact at MTANZ is [ ].

**LifeHealthcare**

65 LHC is a distributor of medical devices which operates across Australia and New Zealand. LHC is ultimately owned by a diverse range of non-associated investors, including funds managed or advised by PEP, an Australian private equity manager. LHC is part of the Pacific Health Group which comprises Pacific Health Supplies TopCo1 Pty Ltd and its subsidiaries.

66 Pacific Health Group's current annual revenue is approximately [ ]. Its total New Zealand revenue for FY2021 was approximately [ ], and only [ ] relates to LHC's New Zealand spinal devices business.

67 Pacific Health Group specialises in (amongst other things):

67.1 through LHC, the distribution of complex medical devices in Australia and New Zealand in therapeutic areas including spine, orthopaedics, interventional neurovascular and neurosurgery, and biologics.[31] In New Zealand, the spinal devices business of LHC overlaps with the spinal devices business of EBOS' Pioneer; and

67.2 through Transmedic (**Transmedic**), the distribution of complex medical devices in Southeast Asia including Singapore, Hong Kong, Indonesia,

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[28] [

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[29] In New Zealand, EBOS is present through its EBOS Healthcare business, which supplies medical products to public and private hospitals, day surgeries, general practitioners, aged care facilities and specialised clinics. EBOS Healthcare has distribution centres located in Auckland and Christchurch (https://www.eboshealthcare.co.nz/about-us/).

[30] See Industry Directory - MTANZ - Medical Technology Association of New Zealand.

[31] Pacific Health Group acquired Culpan Medical in 2020, which distributes interventional neurovascular devices in partnership with Microvention (an OEM). There is no overlap with these devices with EBOS.

Philippines, Thailand, Malaysia and Vietnam in therapeutic areas including spine, orthopaedics, oncology, urology, blood management and IVD;

67.3 specifically in relation to allograft biologics, through its Australian Biotechnologies (**AusBio**) business, the manufacture, processing, product R&D (in Australia) and distribution (in New Zealand and Australia) of human tissue allografts for use in surgeries.

68 LHC's website is at: www.lifehealthcare.com.au, Transmedic's website is at: www.transmedicgroup.com and AusBio's website is at: www.ausbiotech.com.au.

69 LHC is a member of:

69.1 MTANZ,[32] where LHC's main contact is [ ],

69.2 the Medical Technology Association of Australia,[33] where LHC's main contact is [ ], and

69.3 APACMed[34] (via Transmedic) which can be contacted at [ ].

[32] See Industry Directory - MTANZ - Medical Technology Association of New Zealand.

[33] See Industry Members – MTAA – Medical Technology Association of Australia.

[34] See Associate Members – APACMed.

## PART 5: RELEVANT MARKET

### Competitive overlap

70 The only area of overlap between the Parties' business activities in New Zealand is spinal devices and spinal biologics (including synthetic and bio-synthetic bone graft materials).

71 For completeness, the Parties record that both are present in orthopaedics other than spine, but there is no overlap in the products they supply:[35]

71.1 LHC specialises in complex segments for hips, shoulders and knees, for example paediatrics, oncology, limb lengthening and revision arthroplasty,

71.2 Pioneer offers standard hip and knee replacement devices, not devices for complex procedures, and LMT Surgical offers products for use in extremities (hands, wrists, toes and ankles),

71.3 while LMT Surgical supplies synthetic biologic bone graft products (Bonalive and Exabone) for orthopaedics, LHC does not do so in New Zealand, and

71.4 in any event, the Parties supply very small shares of orthopaedics, including sports medicine products, compared to other players (e.g. Pioneer's sales were [ ] in FY21, and LHC approximately [ ], compared with Johnson & Johnson which sells an estimated [ ] each year). Stryker, which supplies direct to customers for its orthopaedic offering, sells an estimated [ ] each year, Zimmer Biomet with estimated sales of [ ] per year and Smith + Nephew with estimated sales of [ ] per year. Each of the top 10 orthopaedic OEMs is represented in New Zealand, either directly or through a distributor.

72 In addition, the parties do not overlap in New Zealand in devices or biologics for other therapeutic areas such as neurosurgery, robotics, or plastics and reconstruction (LHC supplies breast implants, but EBOS supplies only spacing aids and synthetic gels for tissue protections that could be used in plastics and reconstruction procedures).

### Market definition

73 The Parties do not consider it necessary to reach a conclusion on market definition, because the Proposed Transaction will not lessen competition regardless of how any market is defined.

74 However, for the purposes of assessing the competitive effects of the Proposed Transaction the Parties consider it appropriate to adopt a national market for the import and distribution of spinal medical devices and spinal biologics as the relevant market.

#### *Product dimension*

75 On the supply side:

75.1 key suppliers of spinal devices compete to offer to surgeons as full a range of devices as possible, and to introduce new devices to round out their range in

[35] See also below at paragraph 92.

a particular therapeutic area, and/or supply devices using the latest technology (for distributors, this means securing relationships with OEMs that make up a range), and

75.2 the services provided by distributors through qualified sales staff tend to be organised around therapeutic areas. For example, both Pioneer and LHC service the needs of spinal surgeons using a specific and separate sales team due to the knowledge needed regarding the product ranges sold in this therapeutic area.[36] OEMs and/or distributors play a role in educating surgeons about new products that become available, and training surgeons on their use.

76 On the demand side, the decision-maker as to which device to buy is typically the surgeon (although a surgeon will consult his or her patient). As set out above at paragraph 39, this is the case regardless of who ultimately pays for the device.

77 As noted above, complex medical devices, like the spinal devices supplied by the Parties, are highly specialised. Each specific device can only be substituted by alternatives that have been designed for the same application and purpose. The categories of spinal products that the Parties both supply, as well as their competitors, are set out in **Appendix 3**.

78 However, as mentioned at paragraph 40, spinal surgeons use a range of devices as part of their work and rarely use only one supplier's medical devices in all the procedures they perform. This can be, for example, because any preferred supplier (be it an OEM or a distributor) does not supply a particular device required by the surgeon, or because the surgeon considers that another supplier's device is more innovative or achieves better outcomes for their patients. Furthermore, surgeons tend to consult with various OEM and/or distributors' salespeople about their requirements before deciding which devices they require.

79 Accordingly, taking into account both demand- and supply-side considerations, competition for the supply of spinal devices is typically focused across a range of devices in a particular therapeutic area (noting that, within given ranges, specific product offerings can vary significantly and not all OEMs and/or distributors supply a complete range within that therapeutic area – as such, adopting a narrower product market definition would not provide an accurate picture of competitive dynamics, particularly given the limited substitutability of many individual products.

80 Also, as noted above, biologics are separate products, but they are used with specialised spinal devices. Biologics and devices are therefore typically purchased at the same time, although not as a bundle and not necessarily from the same supplier. Surgeons can and do mix and match products and manufacturers

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[36] [ ] [ ]

depending on their requirements. There is not a materially different share of supply, or competitive dynamic, for biologics in New Zealand.

81 For the avoidance of doubt, the Parties do not consider a wider market definition would be appropriate. The distribution of devices in other therapeutic areas has little significance for the competitive dynamic in the supply of spinal devices, and the market definition set out above most closely correlates to, or best exposes, the overlap between the Parties. As above:

81.1 surgeons are specialised and do not purchase devices outside of their specialty areas. As noted, surgeons are the key decision makers. Even where purchases are made by hospitals (which have activities across a number of therapeutic areas), purchases of spinal devices do not tend to be made in conjunction with devices for other therapeutic areas. Specifically, purchase decisions tend to be made by the clinical head of a department (a surgeon), where departments themselves are split by therapeutic area, and purchase decisions are also made based on the specific needs of the patient, and

81.2 the supply of medical devices is specialised by therapeutic area in that sales staff specialise in knowledge of a particular therapeutic area. Both the parties (and, to the parties' knowledge, other suppliers of spinal devices) operate a spinal sales team, which does not supply devices outside of that therapeutic area. For example, when it was set up, Pioneer supplied only spinal devices. Pioneer entered the supply of other orthopaedic devices as a result of a relationship with an OEM (Medacta) that supplied such devices, and did so using separate trained sales staff.

82 In any event, the Parties' sales would comprise a very small share of any wider market. As set out in more detail below (paragraphs 90 to 92), an "all devices" market is estimated to have a value of approximately NZD 1.4 billion, compared with the Parties' sales of [ ] (EBOS, including Pioneer, LMT, Cryomed and MD Solutions) and [ ] (LHC), and the market would comprise approximately 200 competitors. EBOS has estimated an "orthopaedic devices" market would have a value of approximately [ ], of which the Parties' combined share would be [ ] (including EBOS' Pioneer and LMT's [ ] of sales, and LHC's spinal plus orthopaedics revenue of [ ]).

***Geographic dimension***

83 EBOS considers that the appropriate geographic dimension is national. All active OEMs, distributors and the vast majority of funders operate on a national basis. While individual surgeons might operate only in a particular geographic area, conditions of supply and demand do not vary materially across geographies.

84 The supply of spinal medical devices has a material global dimension. Underlying competition is between global OEMs. Additionally, innovation is an important dimension of competition, as OEMs compete to bring to market improved technology, and takes place offshore. Neither Party owns any of the intellectual property associated with the development of the medical devices it supplies (except for Pacific Health Group in allografts[37]).

[37] See paragraph 35.

***Functional dimension***

85 The Parties are active in the distribution of spinal medical devices and spinal biologics in New Zealand, in competition with other distributors and OEMs. Neither Party has any manufacturing facilities in New Zealand. As above, neither Party owns any material intellectual property. Accordingly, the appropriate functional dimension is import and distribution.

***Public/private segmentation***

86 The Parties consider that competitive dynamics are essentially the same across the public and private sectors.

87 In both cases, relevant purchasing decisions are made primarily by surgeons, who tend to offer their services in both the public and private systems and decide on devices and biologics in consultation with their patients. Pricing does not materially differ between the public and private sectors (as set out in more detail below at paragraph 115), and in both cases key drivers of competition include non-price dimensions such as technology and service.

**Market shares**

88 Table 1 below sets out estimated shares of supply of spinal medical devices and spinal biologics in New Zealand, based on value of sales.

**Table 1: Estimated shares of the sales of spinal medical devices and spinal biologics (allografts and synthetic alternatives) in New Zealand[38]**

| Supplier | Spine sales total FY21, including devices and biologics | Share (spine sales totals) | Spine sales total FY21, spine medical devices only | Share of spine (devices) |
|---|---|---|---|---|
| Scionz (Distributor for Medtronic) | [ ] | [ ] | [ ] | [ ] |
| Pioneer (Distributor) | [ ] | [ ] | [ ] | [ ] |
| Life Healthcare (Distributor) | [ ] | [ ] | [ ] | [ ] |
| NuVasive (OEM) | [ ] | [ ] | [ ] | [ ] |
| ORB (Distributor) | [ ] | [ ] | [ ] | [ ] |
| Globus (OEM) | [ ] | [ ] | [ ] | [ ] |
| Zimmer Biomet (OEM) | [ ] | [ ] | [ ] | [ ] |
| Johnson & Johnson (OEM) | [ ] | [ ] | [ ] | [ ] |
| **Merged entity** | [ ] | [ ] | [ ] | [ ] |
| **Totals** | [ ] | [ ] | [ ] | [ ] |

*Source: Estimates based on Pioneer's best estimates (for suppliers other than the Parties) and actual FY21 sales for Pioneer in NZD and LHC, converted to NZD from AUD and rounded to the nearest hundred thousand. There is no objective source of market share data for New Zealand.*

89 [

[38] Market share data for 2019 and 2020 is set out in **Appendix 8**.

]

90 For the reasons given above, the Parties do not consider it would likely assist the analysis to consider a broader market definition. Nevertheless, for context, revenue in New Zealand from all medical devices has been estimated at approximately USD927 million, or approximately NZD 1.4 billion, in 2021.[39] The estimate includes "instruments and machines helping medical service providers in the prevention, diagnosis, and treatment of diseases. The segment covers Cardiology Devices, Diagnostic Imaging, Orthopaedic Devices, Ophthalmic Devices, General & Plastic Surgery Devices, as well as Other Medical Devices."[40] Based on the estimates in the table above, sales of spinal devices (even including associated biologics, which it is not clear are included in the Statista figures) would comprise [ ] of that figure.[41]

91 PHARMAC considers spinal devices to be a sub-category of orthopaedic implants, a category that includes bone substitutes and bone cement (including mixing systems), craniomaxillofacial implants, external fixation devices, hip and knee implants, distal joint implants, power tool consumables associated with orthopaedic instruments, shoulder implants, spinal implants, surgical tools associated with orthopaedic instruments, surgical instrument sets, systems and trays associated with orthopaedic implants and trauma implants.[42] EBOS estimates the value of orthopaedic implants (including spine) to be approximately [ ].[43] Spinal would comprise approximately [ ] of this category by value.[44]

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39 https://www.statista.com/outlook/hmo/medical-technology/medical-devices/new-zealand

40 Ibid.

41 [

]

42 See https://pharmac.govt.nz/hospital-devices/whats-happening-in-each-category/orthopaedic-implants/

43 This estimate is based on:

- the value of spinal sales given in the table above, and
- Pioneer's estimates of the value of sales in the other therapeutic areas.

44 As with the table above, all market data in this section are estimates based on market knowledge (given the lack of third party data sources).

92 In that context:

92.1 for EBOS:

(a) Pioneer's sales of hips and knee devices[45] accounted for approximately [ ] in FY21. See paragraph 71.4 above for an indication of the relative size of this supply,

(b) Cryomed's New Zealand sales were approximately [ ] in FY2021 (approximately [ ]). [

] But large participants in aesthetic devices include Cynasure, Cutera and Candela,

(c) LMT had New Zealand device sales of [ ] (approximately [ ]), which largely comprises devices in the field of sports medicine i.e. supplied to sports clinics rather than orthopaedic surgeons, worth approximately [ ], and extremities (feet, ankle, hand, upper limbs), worth approximately [ ]. EBOS has estimated the total size of the sports medicine market as approximately [ ] and extremities as approximately [ ], and

(d) MD Solutions' supply of medical devices and consumables for interventional oncology, urology and gynaecology, pathology and diagnostics, gastroenterology, and ear, nose and throat procedures in New Zealand generated revenue of approximately [ ] (approximately [ ]). This covers a wide range of therapeutic areas meaning its share of any individual market would be small, and

92.2 LHC's FY2021 New Zealand sales of medical devices and associated biologics can be broken down to:[46]

(a) neurovascular intervention – [ ] (approximately [ ]), against total category sales of approximately [ ],

(b) orthopaedics – [ ] (approximately [ ]) against estimated total category sales of approximately [ ],

(c) plastics [ ] (approximately just over [ ]), against estimated total category sales of approximately [ ],

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[45] [ ]

[46] [ ]

(d) neurosurgery [ ] (approximately just over [ ]), against estimated total category sales of approximately [ ], and

(e) for completeness:

(i) AusBio's sales were [ ] (approximately [ ]) against estimated total sales of spinal biologics of approximately [ ], and

(ii) OR Capital sales were [ ] (approximately [ ]. OR Capital refers to equipment used in the operating room, including operating tables, waste fluid management and surgical instruments. [ ].

**Top suppliers and customers of the Parties**

93 Pioneer's top five OEM suppliers of spinal medical devices and spinal biologics are listed below, by value of Pioneer's sales of these products:

93.1 [ ],[47]

93.2 [ ],[48]

93.3 [ ],[49]

93.4 [ ],[50] and

93.5 [ ].[51]

94 LHC's top five suppliers of spinal medical devices and spinal biologics are:

94.1 [ ],[52]

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[47] [ ]

[48] [ ]

[49] [ ]

[50] [ ]

[51] [ ]

[52] [ ]

94.2 [ ],

94.3 [ ],[53]

94.4 [ ],[54] and

94.5 [ ].[55]

95 Pioneer's top 5 surgeon-customers by approximate value for spinal medical devices and spinal biologics for FY21 were:[56]

95.1 [ ],

95.2 [ ],

95.3 [ ],

95.4 [ ], and

95.5 [ ].

96 LHC's top five surgeon-customers by approximate value for spinal medical devices and spinal biologics for FY21 were:[57]

96.1 [ ],

96.2 [ ],

96.3 [ ],

96.4 [ ], and

96.5 [ ].

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[53] [ ]

[54] [ ]

[55] [ ]

[56] Contact details for Pioneer's top customers are set out in **Appendix 9**. As described above, suppliers focus on surgeons as customers, even though surgeons themselves are not always invoiced for the devices. As such, Pioneer's top customers have been calculated by attributing to a surgeon all revenue associated with devices used by the surgeon, whether the invoice was directed to the surgeon or a hospital. [ ]

[57] As with Pioneer's, LHC's top customers have been calculated by attributing to a surgeon all revenue associated with devices used by the surgeon, whether the invoice was directed to the surgeon or a hospital. Contact details for LHC's top customers are set out in **Appendix 10**.

## PART 6: COUNTERFACTUAL

97 Absent the Proposed Transaction, Pioneer and LHC would continue to compete independently.

## PART 7: COMPETITION ANALYSIS

### Summary – no substantial lessening of competition

98 The key reasons that the Proposed Transaction is incapable of resulting in a lessening of competition in any market in New Zealand are that:

98.1 existing competition, including from Medtronic/Scionz (which supplies a full range of spinal devices and biologics and has almost [ ] of the market), and OEM NuVasive (a globally backed industry leader), will remain robust. There are also a number of other suppliers of spinal devices in New Zealand, including global OEMs such as Globus Medical, Zimmer Biomet and Johnson & Johnson. Their existing presence would constrain the merged entity because they are well-placed to grow their New Zealand presence in response to any theoretical price increases or reduction in quality or service by the merged entity,

98.2 barriers to entry and expansion are demonstrably low, as evidenced by Pioneer's own successful entry into New Zealand in 2015,

98.3 PHARMAC exercises a very material constraint, and each surgeon and underlying funders have significant bargaining power, and

98.4 OEMs can and do bypass distributors and supply directly to customers in New Zealand.

99 For those reasons, if the Proposed Transaction proceeds, the merged entity will face significant competitive constraints, and would have no ability to profitably raise price or decrease service levels.

### Existing competition will remain robust

100 There will remain strong competitors with significant existing market shares following the Proposed Transaction. That is:

100.1 ***Medtronic***, through its distributor Scionz, will remain the largest, and the closest to genuinely full-service, market participant, with approximately [ ] of sales of spinal devices and the backing of the largest global spinal devices company (with global revenue of more than USD 30 billion in FY2021).[58] Medtronic has the largest product range, and currently the most up-to-date range after recently acquiring Medicrea (which as described below in paragraph 121 terminated its distribution agreement with LMT following the acquisition).[59] Medicrea has the latest cutting edge individualised products with 3D printing. Medicrea was recently described as "a pioneer in the transformation of spinal surgery through artificial intelligence, predictive modelling and patient specific implants".[60] Medtronic/Scionz's market position compares with the merged entity's share of supply of up to approximately

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[58] See https://news.medtronic.com/2021-05-27-Medtronic-Reports-Fourth-Quarter-and-Fiscal-Year-2021-Financial-Results-Announces-9-Dividend-Increase

[59] See https://news.medtronic.com/2020-11-16-Medtronic-Completes-Acquisition-of-Medicrea

[60] See https://www.medicrea.com/wp-content/uploads/2020-07-15-MEDICREA-MEDTRONIC_EN.pdf

[ ] [ ] [ ],[61] and

100.2 ***NuVasive,*** another competitor and OEM with significant global backing based in the United States, has a current market share in New Zealand of [ ]. It began in 1997 as a small developer of specialty spinal implants and has grown into a leading medical technology company through its focus on innovation.[62] Its products are sold in over 50 countries, with global net sales of USD 1.05 billion in FY2020. NuVasive has stated that it intends to make investments in infrastructure to further support its existing markets outside of the United States. NuVasive is regarded as the current leader in minimally invasive surgeries.

101 The numerous other suppliers in the market (set out in the market share table above) will also provide a strong and ongoing competitive constraint on the conduct of the merged entity. These include Globus Medical, Zimmer Biomet and Johnson & Johnson, which are all large multinational OEMs, and, respectively, the fifth, sixth and second largest global spine companies.[63] Specifically:

101.1 ***ORB Medical***, a New Zealand owned and operated distributor of medical devices, which sources products from leading companies around the world. It has developed a significant reputation globally, with its website noting that "exciting start-ups as well as larger established medical device companies" have sought to collaborate with ORB to "open up the worthy New Zealand market,"[64]

101.2 ***Globus Medical***, an American manufacturer and distributor of medical devices with products sold in over 31 countries and listed on the New York stock exchange. It has been operating in the musculoskeletal market for over 16 years, offering a broad range of spine products addressing the vast majority of conditions affecting the spine. In FY2020, it earned USD 789 million of net sales globally.[65] In its 2019 Annual report, Globus Medical indicated that it had plans to increase its presence in both existing and new international markets through the continued expansion of direct and distributor sales forces.[66] Globus Medical considers that the musculoskeletal market will continue to experience growth, and intends to leverage its current successes to become the "market leader in providing innovative Musculoskeletal Solutions and Enabling Technologies,"[67]

101.3 ***Zimmer Biomet***, an American manufacturer of medical devices with products sold in over 100 countries. It is listed on both the New York and Swiss stock exchanges, and employs over 20,000 personnel worldwide. In FY2020, it earned USD 7 billion of revenue globally, while its New Zealand revenue alone

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61 [ ] [ ]

62 See https://ir.nuvasive.com/static-files/4119ab36-9e8a-499b-b820-a51666b6f22e

63 See paragraph 33, above.

64 See https://orbmedical.nz/products

65 See https://sec.report/Document/0001562762-21-000036/

66 See https://www.investors.globusmedical.com/static-files/7068e451-8960-4b81-aa3f-0bb8ca8f9ee3

67 At page 6.

was NZD 40 million, supplying from its national head office in Auckland.[68] In its most recent annual report, Zimmer Biomet identified that in upcoming years it intends to pursue growth opportunities in international sales,[69]

101.4 ***Johnson & Johnson***, an American manufacturer of consumer health, pharmaceutical products and medical devices that is listed on the New York stock exchange and supplies virtually all countries in the world.[70] In FY2020, the firm earned USD 23 billion of revenue globally from its medical devices business.[71] Johnson & Johnson manufactures and distributes medical devices through the DePuy Synthes brand in New Zealand and Australia. In FY2020, Johnson & Johnson earned NZD 131 million in revenue across all products (including pharmaceuticals and consumer health products) in New Zealand.[72] At present, Johnson & Johnson is not actively selling in New Zealand as it is switching from direct supply to a distributor model, and the Parties understand that it is in the process of selecting a distributor. But it maintains a strong share of sales in the supply of spinal medical devices in Australia, with estimated sales of [ ]) and has significant resources and capability to expand,

101.5 ***ATEC***, a US NASDAQ-listed company, which has only very recently entered the New Zealand market (as discussed further below). ATEC has a broad spinal product range designed to address the majority of spinal disorders, and

101.6 ***Medacta***, a large multinational OEM based in Switzerland that specialises in orthopaedic and spinal devices and earned more than €300 million in revenue in 2020. [

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102 There are also a number of other suppliers of medical devices in New Zealand that, as far as the Parties are aware, do not currently have a material share of supply of spinal medical devices but could readily expand their presence. These include:

102.1 ***Surgical Innovations*** – EBOS considers that Surgical Innovations is very well placed to expand, with a position comparable to that of Pioneer several years ago. Surgical Innovations was founded in 2014 by two medical device specialists (Ben Diack and Courtney Mackay), and currently specialises in three main areas of orthopaedics: arthroplasty, extremities and infection management. Its spine products are from Ulrich Medical (ADD, ADDplus, Obelisc, Obelisc Pro and VBR), with allografts from Community Tissue

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68 See https://app.companiesoffice.govt.nz/companies/app/service/services/documents/193A44FCEAFC3B1BDE91A718D99EDA0C

69 See https://investor.zimmerbiomet.com/~/media/Files/Z/ZimmerBiomet-IR/documents/annual-reports/2020-annual-report.pdf

70 See https://www.investor.jnj.com/annual-meeting-materials/2020-annual-report

71 See https://www.jnj.com/latest-news/what-you-need-to-know-about-johnson-johnsons-2020-full-year-earnings-report

72 See https://app.companiesoffice.govt.nz/companies/app/service/services/documents/1E8B42B9DF567AC884240BE85A339BCE

Services.[73] Surgical Innovations has 71 products listed in PHARMAC's spinal implants subcategory.[74] Surgical Innovations' owner DBM Medical[75] (also owned by Diack and Mackay) has CB Med whose products appear to include Zimmer Biomet Spine,[76]

102.2 ***Orthotec*** – a privately owned Australia and New Zealand distributor of orthopaedic products, whose spine products include A-Spine, Apifix and FH Ortho (which is part of Olympus).[77] Orthotec has more than 600 products listed in PHARMAC's spinal implants category, across a broad range including screws, plates, rods, cages, hooks and bone void fillers. [ ], which could change if a commercial opportunity presented, and

102.3 ***Surgical Specialties*** – owned by ASX-listed Paragon with 38 products listed in PHARMAC's spinal implants category including Neo kits, screws and rods.[78] Neo is based in Switzerland and the founders are ex-Stryker.[79]

103 Further, the Parties are not each other's closest competitor:

103.1 the Parties, Medtronic/Scionz and NuVasive all offer a range of the relevant products (noting, as above, that Medtronic has the fullest range and NuVasive's latest minimally invasive range has particular benefits, which are resulting in increased sales). Further, all products in which the Parties overlap are substitutable for products supplied by at least one other supplier, although, due to the highly specialised nature of the products, no product range is perfectly substitutable for another, and

103.2 competitive advantage is often gained by updated technology, and in this regard it should be noted that [ ]. In any event, [ ] [ ]

104 The steps outlined below (in paragraph 106) are relevant, to a greater or lesser extent, to these suppliers' potential expansion in spine – noting that these suppliers have relevant experience in New Zealand and/or offshore and are well placed to take those steps.

**Barriers to entry and expansion are low**

105 Barriers to entry and expansion are low. As such, if the merged entity sought to raise price above competitive levels or reduce the quality of its offering, it would be constrained by the potential entry to New Zealand of new OEMs (supplying directly)

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[73] See https://surgicalinnovations.co.nz/about-us/

[74] [ ]

[75] See https://dbm.co.nz/

[76] See https://cbmed.co.nz/

[77] See https://orthotechgroup.net.au/about-orthotech

[78] See http://www.surgicalspecialties.co.nz/

[79] See https://neo-medical.com/the-company/

or distributors (with OEM relationships), as well as the expansion of smaller existing market participants outlined above.

106 The Parties consider that successful entry can occur in a period of less than a year (with expansion of an existing market participant being quicker), and requires:

106.1 ***salespeople:*** the strength of relationships between surgeons and sales teams is important, and salespeople require specialist expertise. Poaching trained sales representatives is a common and accessible method of achieving these relationships and expertise. Re-training a trained salesperson for a new OEM's devices is straightforward and typically at least part-funded by the OEM. Surgeons tend to be open-minded to new products when there are comparable alternatives offered by credible sources. Consistent with this experience, sales representatives frequently move among market participants. For example, the Parties understand that within New Zealand in the past 24 months:

(a) ATEC recruited two employees from LHC;

(b) Surgical Innovations recruited an employee from OrthoMedics (an orthotics and prosthetics manufacturer and distributor);[80] and

(c) NuVasive recruited an employee from Smith + Nephew (a large multinational manufacturer of a range of products, including orthopaedic/arthroscopy products for hips, knees and shoulders)[81].

Given that product knowledge is one of the few requirements, OEMs are not limited to salespeople based in New Zealand, and may instead recruit salespeople from overseas. Pioneer considers it reasonable to assume an approximate lead time for obtaining new salespeople of four months (comprising one month's notice and allowing for a restraint of approximately three months). Additional training of salespeople can take approximately three months depending on prior experience, and is likely to be at least partly funded by OEMs. Training may take place during the restraint period (training is not typically prevented by restraints).

106.2 ***OEM relationship:*** a new entrant that does not manufacture products itself would need time to negotiate an agreement with one or more OEMs. [ ],

106.3 ***registration:*** there are no material regulatory barriers to entry. Devices must be registered on the WAND database before being distributed in New Zealand. This is also one of the requirements of PHARMAC's terms and conditions.[82] However, Medsafe does not impose requirements for approval[83] (in practice, suppliers rely on regulatory approvals from jurisdictions perceived as trustworthy, such as the United States of America or Australia, to persuade surgeons of the credentials of devices they offer). The process of WAND registration takes approximately 48 hours, and

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80 See https://orthomedics.com/about/

81 See https://www.smith-nephew.com/about-us/what-we-do/

82 See clause 7.1(b) [ ] – see above n 18.

83 See https://www.medsafe.govt.nz/regulatory/DevicesNew/3-2Explanation.asp.

106.4 ***funding:*** PHARMAC funding is accessible for all registered products, and surgeons' choices tend to be accepted by health insurers (and patients).[84] So while PHARMAC funding is not technically required for supply to the private sector only, in practice it is typically obtained. From a practical perspective, it is a relatively straightforward process to have a product included in PHARMAC's funding schedule, particularly for a supplier that already has a relationship contact at PHARMAC.[85]

107 Many of the above activities would be able to be undertaken concurrently.

108 To illustrate, recent examples of entry and expansion include:

108.1 Pioneer entered the market in 2015 and has since secured a share of supply of approximately [ ], demonstrating that entry and expansion are readily achievable. [

], and

108.2 ATEC, a US NASDAQ-listed company, has very recently entered the New Zealand market.[86] ATEC has a broad spinal product range designed to address the majority of spinal disorders. All but one of its executive leadership team are ex-NuVasive employees.[87] ATEC is an example of how a new supplier can enter by poaching experienced sales representatives from existing New Zealand supplier, and as those sales representatives have established relationships with surgeons they will be able to bring them across to the new entrant.[88]

109 In addition to these examples, and the existing smaller market participants that could readily expand (as described in paragraph 102):

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84 See https://pharmac.govt.nz/hospital-devices/about-our-role-in-device-management/

85 It is also possible for new products to be supplied at the request of a surgeon. If a surgeon becomes aware of a new product that they wish to trial (and which is not already on the PHARMAC schedule), they can engage with the supplier and the relevant hospital to confirm that the product can be supplied in New Zealand (i.e. is MedSafe WAND registered), the surgeon can trial the product on one or more patients. If successful, the surgeon can request the hospital to make the product available. This could be achieved by getting it on the PHARMAC schedule, or by negotiation (with a private hospital).

86 ATEC sold its international business to Globus Medical in 2016, which included a supply agreement through which ATEC will supply its products to Globus until August 2021. ATEC agreed to not compete in the international market for the term of the supply agreement plus an additional two years (i.e. August 2023). See more details in ATEC's 2020 Annual Report available at https://investors.alphatecspine.com/sec-filings/default.aspx.

87 See https://atecspine.com/about/#leadership

88 For further information, see https://atecspine.com/

109.1 there are spine OEMs that do not currently supply products in New Zealand, such as Nexxt Spine (a US company) and Biedermann Motech (a German company), which could enter directly or via experienced distributors such as Obex. Nexxt Spine and Biedermann Motech are emerging suppliers but are growing in popularity. Biedermann Motech is mid-sized on a global scale and specialises in spinal devices (amongst other things),

109.2 Obex and Universal Specialities Limited are credible medical devices/biologics distributors that are already in New Zealand, but not yet in spine, and

109.3 Joy Surgical (which distributes Centinel Spine products) is an example of a credible spine devices and biologics distributor which appears to have the rights for Australia and New Zealand but is not yet active in New Zealand, although it has a New Zealand-registered company.

**There is significant countervailing bargaining power**

110 Importantly, pricing is materially constrained by PHARMAC, across both the public and private sectors (see above at paragraph 43 and following), and this will be unaffected by the Proposed Transaction.

111 Given the way that PHARMAC provides funding for medical devices in New Zealand, the merged entity will be constrained in its ability to raise prices. Specifically:

111.1 for devices already funded by PHARMAC, PHARMAC's consent is required for any price rise. PHARMAC has no incentive to consent to a price rise above competitive levels given the number of other existing and potential suppliers it could turn to for the supply of devices as an alternative to the merged entity. [

] and [

], and

111.2 [

]

112 [ ], PHARMAC pricing becomes a competitive benchmark across the public and private sectors. Surgeons generally work across the public and private sectors and therefore have visibility of PHARMAC pricing. They tend to seek to purchase devices at, or with a clear link to, PHARMAC prices which constrain prices for all surgeries (i.e. funded by ACC, health insurers or privately by patients themselves). [

]

113 In addition to the constraint provided by surgeons, ACC and health insurers are aware that a large number of devices are PHARMAC funded and expect their private sector pricing to reconcile with the PHARMAC prices. This expectation is conveyed to suppliers through the surgeons with whom they have a relationship.

114 [

]

115 The benchmarking function of PHARMAC pricing will not change as a result of the Proposed Transaction, as the surgeons (as well as ACC and health insurers) will continue to have visibility of PHARMAC pricing and be unwilling to agree to higher pricing unless convinced of the reason. Their ability to do so will continue to be buttressed by the fact that there will continue to be a concentrated customer group (see below) with a number of suppliers to choose from.

116 In addition to the role of PHARMAC, surgeons are key decision-makers in both the public and private sectors. The surgeon-customer base for spinal devices is concentrated, with the majority of sales made to a small number of surgeons. In total, there are only approximately [ ] spinal surgeons in New Zealand. Surgeons' selection of specific products for specific patient applications means that purchasing decisions are primarily clinical ones. Surgeons have real bargaining power.

117 In particular:

117.1 as above, visibility of PHARMAC prices by surgeons working across the public and private sectors means surgeons are able to benchmark their pricing with a competitive level,

117.2 there are no formal contractual requirements stopping surgeons from switching distributors or OEMs. Sales are typically through individual purchase orders, and there are no long-term contracts,

117.3 surgeons can and do switch. While suppliers attempt to offer as full a range as possible, none offers devices covering all types of surgery, with the Medtronic/Scionz coming closest. Further, there is a significant role for innovation, as OEMs and distributors compete to offer new technology. As such, surgeons tend to maintain relationships with more than one sales team. Furthermore, trained sales staff can and do move around. If a sales representative with whom a surgeon has a close relationship switches to another supplier, the surgeon may continue to deal with the representative at their new employer, and also potentially maintain the relationship with the former employer's wider sales team (with which the surgeon also has a relationship). For example, [

], and

117.4 surgeons are accustomed to adopting new devices (and suppliers). Surgeons who practice in this area in New Zealand are widely considered to be innovators who are open to change and driven by constant improvement.

**OEMs can and do bypass distributors**

118 As an alternative to using distributors such as Pioneer and LHC, many OEMs resource their required distribution services in-house. For example, [

]. It is not uncommon for OEMs to adopt different strategies for different products within

their range, and appoint different distributors for (and within) different countries.[89] For example, an OEM may have a large portfolio of products in a certain therapeutic area or a product in a large therapeutic area that commercial considerations would favour a direct presence, but may also have a product/s in another therapeutic area that does not offer enough scale to have a direct presence.[90]

119 Further, OEMs can "go direct", or threaten to do so, if they are not content with their existing distribution arrangements – to EBOS' knowledge, contractual terms tend to be [

].

[ ]

120 Arthrex, a global medical device company and leader in orthopaedics and sports medical devices (with approximately NZD 25 million sales of orthopaedic devices in New Zealand) in 2020 changed from a distribution model (represented by Device Technologies) to a direct model in New Zealand.[91] [

] Distributors are disincentivised from lowering service levels or engaging in conduct that would increase the likelihood of OEMs seeking to commence direct supply or replace the distributor.

121 In addition, distributors of medical devices are vulnerable to OEMs they represent being acquired by another large global OEM, which (depending on the particular distribution contract terms) following the Proposed Transaction can potentially terminate the distribution relationship and allow them to go direct. This happened recently to LMT Surgical, which was the Australia and New Zealand distributor for Medicrea (a spinal device OEM), which was acquired by Medtronic in 2020.[92] Following the acquisition, Medicrea (as part of Medtronic) terminated that distribution agreement. [

].

122 New entrants could also consider a "hybrid" model, e.g. a local agent responsible for logistics, but with an OEM retaining control of other functions such as marketing,

---

89 Some OEMS also adopt a hybrid model whereby they engage a distribution agency for logistics functions only, while retaining control of all other functions (such as sales, marketing and regulatory), which is another available alternative to access the market.

90 It is common for distributors to enter into distribution agreements with OEMs that do not have an existing presence in New Zealand, for example:

- that is how Pioneer established itself – by bringing to market the products of OEMs (such as Medacta) with no existing presence New Zealand,
- LHC with 4WEB, Misonix and Orthofix,
- ORB with Orthopaediatrics, and
- Orthotech with A-Spine.

But for completeness note that it is rare for New Zealand distributors to source products for surgeons from OEMs on a one-off basis and where there is no distribution agreement in place with the OEM.

91 See https://discover.arthrex.de/WP20-000761-en-AU-GLP-Australia_WP20-000761-en-AU---Enterprise.html

92 See https://news.medtronic.com/2020-11-16-Medtronic-Completes-Acquisition-of-Medicrea

sales and regulatory (although this model is more typically associated with distribution of commodity and pharmaceutical medical products).

**No vertical, conglomerate or coordinated effects**

***No vertical effects***

123 For completeness, the Parties confirm that the Proposed Transaction will not result in any vertical integration.[93]

***No conglomerate effects***

124 The Parties currently have no ability to tie or bundle products together in a way that would artificially distort or lessen competition (or foreclose a competitor), and the Proposed Transaction would have no effect on that ability. Neither Pioneer nor LHC have any "must have" devices, or biologics, that could be leveraged or bundled. Devices are necessarily purchased individually, and surgeons choose which devices are most appropriate from a therapeutic point of view. As noted above, it is surgeons that have the most influence in driving purchasing decisions.

125 Even following the Proposed Transaction, no single supplier is likely to be able to meet all the therapeutic area needs of a particular surgeon-customer (Medtronic/Scionz would be closest to being able to do so). The merged entity's product range would not be unique, but rather comparable to other key suppliers.

126 For completeness, note that there is no potential for conglomerate effects across medical devices in different therapeutic areas. Purchasing decisions are made by clinicians (even in hospitals whose activities range across various therapeutic areas) and such clinicians have no interest in or knowledge of products that are suitable for other types of surgeries – purchases tend to be made in particular therapeutic areas, and not across such areas. Furthermore, in relation to the public sector, to the Parties' knowledge, PHARMAC does not accept offers in "bundles" of products.[94]

***No coordinated effects***

127 There would be no increased potential for coordination. Having regard to the factors at paragraph 3.89 of the Mergers and Acquisitions Guidelines, none of which would change following the Proposed Transaction:

127.1 The products are highly specialised and specific to their application and to the patient.

127.2 There are a large number of actual and potential competitors.

127.3 Firms do not typically transact with one another.

127.4 The market comprises firms of different sizes and cost structures. In that sense, OEMs are very different from distributors and New Zealand companies are different from multinationals.

127.5 There is a high degree of innovation for medical devices and biologics with a strong research and development pipeline.

---

[93] Note that LHC currently supplies some AusBio biologics products manufactured in Australia to customers in New Zealand. However, the Proposed Transaction does not increase the degree of vertical integration, nor does it create any vertical integration in New Zealand.

[94] See, for example, https://pharmac.govt.nz/assets/rfp-2021-11-02-surgical-instruments.pdf at 5.2(a).

127.6 Firms cannot readily observe other's prices and volumes.

127.7 As far as the Parties are aware, there are no material interrelationships through association or cross-partial ownerships.

128 Taken together, the above factors mean that there is no opportunity for coordination irrespective of the Proposed Transaction.

## PART 8: CONFIDENTIALITY

129 Confidentiality is sought in respect of the information in this application that is highlighted (**Confidential Information**). Confidentiality is sought for the Confidential Information for the purposes of section 9(2)(b) of the Official Information Act 1982 on the following grounds:

129.1 the Confidential Information is commercially sensitive and valuable information which is confidential to either, or both, Parties, and

129.2 disclosure of the Confidential Information would be likely to unreasonably prejudice the commercial position of the Parties.

130 The Parties request that they are notified if the Commission receives any request under the Official Information Act 1982 for the release of any part of the Confidential Information. They also request that the Commission seek and consider their views as to whether the Confidential Information remains confidential and commercially sensitive before it responds to such requests.

## DECLARATION BY EBOS

I, Janelle Cain, have prepared, or supervised the preparation of this notice seeking clearance.

To the best of my knowledge, I confirm that:

- All information specified by the Commission has been supplied;
- If information has not been supplied, reasons have been included as to why the information has not been supplied;
- All information known to the applicant that is relevant to the consideration of this notice has been supplied; and
- All information supplied is correct as at the date of this notice.

I undertake to advise the Commission immediately of any material change in circumstances relating to the notice.

I understand that it is an offence under the Commerce Act to attempt to deceive or knowingly mislead the Commission in respect of any matter before the Commission, including in these documents.

I am a director/officer of EBOS Medical Devices Australia Pty Ltd and am duly authorised to submit this notice.

**Name and title of person authorised to sign:**

**Janelle Cain, Company Secretary**

**On behalf of EBOS Medical Devices Australia Pty Ltd**

**Sign:** _____

**Date:** _____

## TABLE OF APPENDICES

| Appendix | Document |
|---|---|
| 1 | [Confidential] Share Sale Agreement |
| 2 | [Confidential] Structure diagram for the target |
| 3 | Spinal medical devices and biologics supplied by the Parties |
| 4 | Contact details for the Parties' key competitors |
| 5 | [Confidential] Terms and conditions on which Pioneer has agreed to supply the products it distributes to DHBs |
| 6 | PHARMAC RFP for orthopaedic devices (April 2016) |
| 7 | PHARMAC's current list of funded spinal devices |
| 8 | [Confidential] Market share estimates |
| 9 | [Confidential] Contact details for Pioneer's key customers |
| 10 | [Confidential] Contact details for LHC's key customers |
| 11 | [Confidential] [ ] |
| 12 | [Confidential] Pioneer Medical Limited Financial Report for the Year Ended 31 March 2021 |
| 13 | [Confidential] Pioneer Medical Ltd 2021 Management Report |
| 14 | [Confidential] Pacific Health Supplies HoldCo Pty Limited FY21 Final Accounts |

## APPENDIX 1: [CONFIDENTIAL] SHARE SALE AGREEMENT

[ ]

## APPENDIX 2: [CONFIDENTIAL] STRUCTURE DIAGRAM FOR THE TARGET

[ ]

## APPENDIX 3: SPINAL MEDICAL DEVICES AND BIOLOGICS SUPPLIED BY THE PARTIES

| Device | Overview | Typical image |
|---|---|---|
| **Pedicle screws / bone screws** | A pedicle or bone screw is used to hold vertebrae (individual bones which form the spinal column) and bone graft (bone tissue) together to promote healing as part of spinal fusion, where two or more vertebrae are fused together, immobilizing them to create a single, continuous bone. Spinal fusion treats broken vertebra, spinal deformities, spinal weakness, spinal instability, or chronic low back pain.[95] Screws can be used alongside other products, such as cages or disk replacements. |  |
| **Posterior/lateral cages** | Posterior or lateral cages hold bone graft during spinal fusion and act as a space holder between two vertebrae. They become part of the spine and are placed around a set of discs to encourage bone growth. Cages are made of plastic, carbon fibre or metal.[96] |  |
| **Disc replacements** | Disc replacements are designed to replicate the anatomic structure and performance of a natural disc.[97] |  |
| **Plates and rods** | Metal plates and rods (together with screws) are used in spinal fusion surgery to help hold the vertebrae together, so that they can heal into one solid unit.[98] |  |

[95] https://www.lifehealthcare.com.au/wp-content/uploads/2016/05/RENAISSANCE_TRIFOLD_SPINAL_FUSION_HR.pdf and picture from: https://www.lifehealthcare.com.au/products/serrato/

[96] https://www.lifehealthcare.com.au/wp-content/uploads/2016/05/RENAISSANCE_TRIFOLD_SPINAL_FUSION_HR.pdf and picture from: https://www.lifehealthcare.com.au/products/tritanium-c/

[97] https://www.lifehealthcare.com.au/products/m6l/.

[98] https://www.lifehealthcare.com.au/products/caspian-mini-mesa-mini-denali/ and https://www.lifehealthcare.com.au/products/ozark/

| Device | Overview | Typical image |
|---|---|---|
| **Navigation aids** | Navigation aids help surgeons plan and carry out spinal surgeries. Surgeons can see where their instruments are and virtual images of the spine on a display. These aids enable surgeons to carry out surgeries with increased accuracy and less radiation exposure. |  |
| **Biologics** | Biologics are engineered materials designed to stimulate and promote the healing of fractures and other bone defects, such as bone grafts or bone graft substitutes to fill voids or gaps (for example in the space between two spinal vertebrae during spinal fusion surgery). They may be produced from the patient themselves (autografts), donated human tissue (allografts), demineralised bone and demineralised bone matrix (are effectively allograft bones that have been decalcified by acid extraction) or from synthetic alternatives.<br><br>Different biologics can be used together and alongside other products as an accessory during procedures such spine surgery. |  <br>  |

## APPENDIX 4: [CONFIDENTIAL] CONTACT DETAILS FOR THE PARTIES' KEY COMPETITORS

| Competitor | Contact details |
|---|---|
| Medtronic/Scionz | [ ] |
| NuVasive | [ ] |
| ORB Medical | [ ] |
| Globus Medical | [ ] |
| Zimmer Biomet | [ ] |
| Johnson & Johnson / DePuy Synthes | [ ] |

## APPENDIX 5: [CONFIDENTIAL] TERMS AND CONDITIONS ON WHICH PIONEER HAS AGREED TO SUPPLY THE PRODUCTS IT DISTRIBUTES TO DHBS

[ ]

## APPENDIX 6: PHARMAC RFP FOR ORTHOPAEDIC DEVICES (APRIL 2016)

Attached separately.

## APPENDIX 7: PHARMAC'S CURRENT LIST OF FUNDED SPINAL DEVICES

Attached separately.

## APPENDIX 8: [CONFIDENTIAL] MARKET SHARE ESTIMATES

Given that there is no objective source of market share data for New Zealand:

- Both of the following tables have been compiled from Pioneer's and LHC's actual sales in the relevant financial year for Pioneer in NZD, and LHC converted to NZD from AUD and rounded to the nearest hundred thousand.

- Estimates for other competitors have been reached on the basis of [

  ].

| Supplier | Spine sales, including devices and biologics | | | | | |
|---|---|---|---|---|---|---|
| | FY2019 | | FY2020 | | FY2021 | |
| | Revenue | Share of supply | Revenue | Share of Supply | Revenue | Share of Supply |
| Scionz (Distributor for Medtronic) | [ ] | [ ] | [ ] | [ ] | [ ] | [ ] |
| Pioneer (Distributor) | [ ] | [ ] | [ ] | [ ] | [ ] | [ ] |
| Life Healthcare (Distributor) | [ ] | [ ] | [ ] | [ ] | [ ] | [ ] |
| NuVasive (OEM) | [ ] | [ ] | [ ] | [ ] | [ ] | [ ] |
| ORB (Distributor) | [ ] | [ ] | [ ] | [ ] | [ ] | [ ] |
| Globus (OEM) | [ ] | [ ] | [ ] | [ ] | [ ] | [ ] |
| Zimmer Biomet (OEM) | [ ] | [ ] | [ ] | [ ] | [ ] | [ ] |
| Johnson & Johnson (OEM) | [ ] | [ ] | [ ] | [ ] | [ ] | [ ] |
| Total | [ ] | [ ] | [ ] | [ ] | [ ] | [ ] |

| Supplier | Spine sales, spine medical devices only | | | | | |
|---|---|---|---|---|---|---|
| | FY2019 | | FY2020 | | FY2021 | |
| | Revenue | Share of supply | Revenue | Share of Supply | Revenue | Share of Supply |
| Scionz (Distributor for Medtronic) | [ ] | [ ] | [ ] | [ ] | [ ] | [ ] |
| Pioneer (Distributor) | [ ] | [ ] | [ ] | [ ] | [ ] | [ ] |
| Life Healthcare (Distributor) | [ ] | [ ] | [ ] | [ ] | [ ] | [ ] |
| NuVasive (OEM) | [ ] | [ ] | [ ] | [ ] | [ ] | [ ] |
| ORB (Distributor) | [ ] | [ ] | [ ] | [ ] | [ ] | [ ] |
| Globus (OEM) | [ ] | [ ] | [ ] | [ ] | [ ] | [ ] |
| Zimmer Biomet (OEM) | [ ] | [ ] | [ ] | [ ] | [ ] | [ ] |
| Johnson & Johnson (OEM) | [ ] | [ ] | [ ] | [ ] | [ ] | [ ] |
| Total | [ ] | [ ] | [ ] | [ ] | [ ] | [ ] |

## APPENDIX 9: [CONFIDENTIAL] CONTACT DETAILS FOR PIONEER'S KEY CUSTOMERS

| Customer | Value of sales FY21[99] | Contact details |
|---|---|---|
| [ ] | [ ] | [ ] |
| [ ] | [ ] | [ ] |
| [ ] | [ ] | [ ] |
| [ ] | [ ] | [ ] |
| [ ] | [ ] | [ ] |
| [ ] | [ ] | [ ] |
| [ ] | [ ] | [ ] |

[99] [

]

## APPENDIX 10: [CONFIDENTIAL] CONTACT DETAILS FOR LHC'S KEY CUSTOMERS

| Customer | Value of sales FY21 | Contact details |
|---|---|---|
| [ ] | [ ] | [ ] |
| [ ] | [ ] | [ ] |
| [ ] | [ ] | [ ] |
| [ ] | [ ] | [ ] |
| [ ] | [ ] | [ ] |

## APPENDIX 11: [CONFIDENTIAL] [ ]

[ ]

## APPENDIX 12: [CONFIDENTIAL] PIONEER MEDICAL LIMITED FINANCIAL REPORT FOR THE YEAR ENDED 31 MARCH 2021

[ ]

## APPENDIX 13: [CONFIDENTIAL] PIONEER MEDICAL LTD 2021 MANAGEMENT REPORT

[ ]

## APPENDIX 14 – [CONFIDENTIAL] PACIFIC HEALTH SUPPLIES HOLDCO PTY LIMITED FY21 FINAL ACCOUNTS

[ ]