Australian Government
Department of Health

Prostheses List Reforms – Consultation Paper Nº 1

Prostheses List – Purpose, Definitions, and Scope

Context for the consultation paper

In the 2021-22 Federal Budget, the Australian Government committed $22 million over four years for the *Modernising and Improving the Private Health Insurance Prostheses List* Budget measure. Following extensive consultation over recent years, this consultation paper will canvass views on proposed implementation of improvements to the Prostheses List (PL) as announced in the Budget. The Government considers these improvements are necessary to benefit consumers, because a number of reviews of the system have consistently found a high variance in the prices on the PL compared to prices paid in the public hospital system, with a limited ability for market forces to exert a downward pressure that would benefit consumers. In addition, while the medical technology industry has committed in recent years to modest price reductions, the benefit to consumers of these reductions has been eroded by significant increases in the volumes of items being claimed.

The PL improvements are part of a major multi-year reform to the health technology assessment (HTA) processes within the Department of Health to address capability limitations and position HTA for future needs. Central to the HTA uplift is the development of the Health Products Portal (HPP) which is a single, secure and easy to use platform through which industry can interact with Government to apply, track, pay for and manage listings for regulated and subsidised health-related products and services.

The HPP will provide significant regulatory savings to industry, across a range of categories which build on each other over time to realise cumulative benefits. Once the project is fully implemented, the estimated savings to the pharmaceutical and medical device industry will be around $157 million annually. This estimate is based on digitisation of approximately 8,000 interactions per year between industry and government.

The development of the HPP together with the PL improvements, provide the opportunity for streamlining processes and ensuring the PL, which has been a feature of the Australian health system since 1985, meets consumer expectations.

The PL improvements propose a number of changes to the PL processes to improve transparency, increase consumer protection and address sustainability of the system of reimbursement through private health insurance. While this first paper focuses on the purpose, definitions, and scope (criteria for listing) of the PL, future consultation papers will discuss the following proposed features:

- restructured Part A and Part C of the PL with the streamlined grouping structure
- a revised Part B of the PL
- disclosing actual prices paid for PL items in the Australian public sector
- comparison of PL prices with the prices in comparable international markets such as Canada, France, New Zealand, Singapore, United Kingdom, and the United States
- introducing, as a part of PL application process, a declaration by companies that there will not be extra charges for the products beyond the PL price, with penalties for false declaration, to ensure no out-of-pocket expenses for consumers, and
- other suitable compliance approaches to maintain the integrity of the program.

The PL improvements will benefit private health insurers by lowering prices paid by insurers for medical devices. This benefit will flow to Australians with private health insurance by keeping downward pressure on premiums. Doctors, private hospitals and privately insured patients will benefit through continued access to a comprehensive range of medical devices and certainty about their reimbursement.

Medical device companies will also benefit from the PL streamlined administration with new pathways for listing devices on the PL.

Purpose

As announced in the Budget measure, a key element of the reforms is to improve the administration of the PL and address issues raised by recent reviews relating to the PL scope and operation.

The purpose of this paper is to clarify details of the government's decision to better define the PL purpose, definitions, and scope and explore how this might be implemented in delegated legislation and the guidance.

It is proposed that the definition and listing criteria will be more clearly defined regarding which products are eligible for listing on the PL.

As a consequence of this change, certain general use products (mainly listed in Part A of the General Miscellaneous Category) will no longer be eligible for having their price set by a listing on the PL. It is also expected that some products currently not meeting the PL criteria will become eligible for listing. Based on consultation to date it is expected that market competition and direct contracting will result in more efficient prices and contracting arrangements,

The paper is seeking comments on the changes related to the definition and revised listing criteria, and clarification on the eligibility of some products for listing on PL.

Other issues for consideration include the name of the PL and whether it accurately reflects the products we refer to, and better alignment with the terminology used in the therapeutic goods legislation.

This consultation paper builds on the previous reform and review activities, including the reforms under the Australian Government's 2017 Agreement with the Medical Technology Association of Australia[1] (MTAA Agreement), in particular the work of:

- the Quality of Information and Guidance Industry Working Group
- the Revised Benefit Setting & Review Framework Industry Working Group
- the Review of the General Miscellaneous Category of the Prostheses List
- the Review of Part B (Human Tissue) of the Prostheses List.

This consultation process will inform the development of legislative amendments.

Prostheses List – the existing arrangements

The *Private Health Insurance Act 2007* (the PHI Act) is the primary legislation regulating private health insurance, including the PL arrangements. The PHI Act requires private health insurers to pay prices listed in the PL to patients with appropriate private health insurance cover for approved kinds of prostheses received as part of the hospital or hospital-substitute treatment, for which a Medicare benefit is payable.

The *Private Health Insurance (Prostheses) Rules* (the Prostheses Rules) is a legislative instrument made under the PHI Act, that sets up requirements in relation to provision of minimum price for prostheses. The Schedule to the Prostheses Rules is known as the PL. (Note that the amount listed on the PL is technically a benefit amount, but because it is the amount that insurers are legally required to pay, it is also effectively the price and the term "price" will be used in this paper).

[1] Agreement between the Government and the Medical Technology association of Australia, https://www.health.gov.au/resources/publications/agreement-between-the-government-and-the-medical-technology-association-of-australia

The Prostheses Rules may provide criteria for listing (*listing criteria*) which must be satisfied (if set up in the Rules) in order for the device to be eligible for listing on the PL.

Definition

Currently, a **prosthesis** is not explicitly defined but is taken as a product of a kind listed in the Schedule of the Prostheses Rules[2].

Listing criteria

The PHI Act sets out several requirements when a price is payable with respect to prostheses. In line with this, private health insurers are required to pay a price for a product if:

- The product is listed on the PL.
- The patient receives the product as part of hospital treatment or hospital substitute treatment.
- The patient has appropriate health insurance to cover for the treatment.
- A Medicare benefit is payable for a service associated with the use of the product.

These existing legislative requirements apply to any prostheses listed on the PL.

The types of prostheses covered by the PL are also expected to be those that meet the criteria for listing.

The Prostheses List is currently comprised of three parts (Part A, Part B, and Part C) with different criteria for listing (PL criteria) for each part.

The PL criteria for Part A and Part B are provided in the *Prostheses List - Guide to listing and setting benefits for prostheses*[3] (the PL Guide).

The PL Guide also provides that prostheses are a subset of medical devices, and human tissues items (biologicals).

Products listed in any part of the PL are expected to be used for therapy (treatment or alleviation of disease or compensation for an injury or disability), not for diagnosis, prediction, or prognosis, though there are some examples where this is not the case (e.g. cardiac event recorders and remote monitors for cardiac devices).

Part A

The Part A criteria for listing, in addition to the PHI Act requirements include:

- The product is to be entered on the Australian Register of Therapeutic Goods (ARTG).
- The product should be surgically implanted (intended to replace an anatomical body part, or combat or modulate a physiological process), or be essential and specifically designed as a single-use aid for implanting a prosthesis, or be critical for maintaining ongoing-function of the surgically implanted prosthesis.
- The product should be at least of similar clinical effectiveness and cost effectiveness compared to alternative products on the PL or alternative treatments[4].

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[2] Subsection 72-1(2), item 4 of the *Private Health Insurance Act 2007*
[3] Prostheses List – Guide to listing and setting benefits for prostheses, February 2017, Revision 3, https://www.health.gov.au/resources/publications/prostheses-list-guide
[4] Prostheses List - Guide to listing and setting benefits for prostheses, pp. 13-16

The products listed on Part A are expected to be medical devices.

Part B

The products eligible for listing on Part B are human tissue items (biologicals) used for replacement of anatomical parts (e.g. corneas, bones, and heart valves)[5].

Part C

The Part C criteria are set up in the Prostheses Rules and provide types of medical devices eligible for listing (including insulin infusion pumps, cardiac loop recorders, cardiac home/remote monitoring systems, and cardiac ablation devices). These devices do not meet the Part A criteria but have been approved by the Minister for listing and some of them have been assessed as addressing unmet clinical need and as being clinically effective and cost effective by the Medical Services Advisory Committee (MSAC) (e.g. cardiac ablation devices and implantable cardiac event recorders).

The products listed on Part C are expected to be medical devices.

Scope and definitions – proposed amendments

What was proposed?

The statement included in the Government's 2021-22 Federal Budget on purpose and scope of the PL was based on the following proposal that appeared in *the Consultation Paper: Options for reforms and improvements to the Prostheses List*.

> It is proposed that benefits be payable for specific purpose medical devices where the intention of the accompanying medical procedure is to remedy disease or dysfunction through use of the specific medical device (e.g. hip replacement, stent, balloon angioplasty). The device should not be one that is used as an adjunct to the procedure (e.g. sutures, haemostatic agents, adhesives).
>
> It should be noted that this definition no longer requires that the device be implanted but retains the requirement that the device be therapeutic. The focus is on the device being one that is intended to remedy a medical condition.
>
> A consequence of confining scope as proposed would be that most general use medical devices and consumables would no longer be funded through the PL, but would continue to be funded through other mechanisms, such as contracts between insurers and hospitals.

What does it mean?

Definition

For the purposes of improving clarity and transparency, it is proposed that a definition of a kind of prosthesis is included in the PHI legislation, and will specify that:

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[5] Prostheses List - Guide to listing and setting benefits for prostheses, p. 56

a **medical device** or **human tissues item** (**biological**) intended to be used for **therapy** and that meets the ***criteria for listing*** as set up in the Prostheses Rules is declared to be a kind of prosthesis for the purposes of the PHI Act if **it is listed in Schedule of the Prostheses Rules**.

Therapy includes monitoring, treatment or alleviation of disease or compensation for an injury or disability.

The terms 'medical device' and 'biological' have the meaning as defined under the *Therapeutic Goods Act 1989 (TG Act).*

Human tissue prosthesis means a product that is substantially derived from human tissue where the tissue has been subjected to processing or treatments and the supply (however described, including trade, sell, give or gift) of which is governed by state or territory law (as defined in the *Private Health Insurance (Prostheses Application and Listing Fee) Rules 2018*).

The legislation will also specify that a medical device or biological (human tissues item) will no longer be a kind of prosthesis if it is removed from the Prostheses Rules, including if it no longer meets the criteria for listing.

The Prostheses Rules and the Guide will further clarify that a kind of prosthesis is to be uniquely identified by the product name, description and other information entered on the PL. If a product is a system or procedure pack under the TG Act (e.g. a kit containing multiple components), it is a kind of prosthesis for the purposes of the PL.

Medical devices or human tissue items intended for use for diagnosis, prediction, or prognosis are expected to remain ineligible for listing on PL.

Many diagnostic devices are used in an ambulatory setting within diagnostic imaging and pathology practice. The PL has never been intended to cover for these types of devices and there are no plans to change it.

If there are any exceptional circumstances, those devices will need to be considered under Part C (refer section below on the criteria for listing for Part C).

Criteria for listing

Many of the existing arrangements are expected to continue for all prostheses seeking to be listed on the PL, that is:

- The current requirements specified in the PHI Act [private health insurance cover for approved kinds of prostheses, hospital treatment, and availability of the Medicare services].
- The expectation that devices or human tissues are used for therapy, not diagnosis.
- The requirement for the inclusion of a medical device or biological in the ARTG.

In relation to the ARTG entry, it is proposed that this criterion will be clarified so that the information entered on the ARTG entry [on the intended purpose and, where applicable, functional description of the device, or indication] is to be consistent with the information entered on the PL [product name, description, purpose, and grouping]; this will clarify that the price is payable for the prosthesis as authorised for supply by the TGA.

It is also likely that the criteria and process for removing items from the PL will be included in the legislative changes.

Part A

Part A criteria for listing will be specified in the Prostheses Rules and clarified with some amendments implemented.

The existing requirements will continue to apply, but it is proposed that both the implantable medical devices and single-use short-term or long-term surgically invasive medical devices for a specified therapy will meet the listing criteria. The devices are to be intended for monitoring, treatment or alleviation of a particular disease or compensation for an injury or disability, or replacement or modifying the anatomy or a physiological or pathological process or state, and are used within a surgical (or other interventional) procedure.

The above proposed change clarifies that in addition to implantable medical devices, some single-use surgically invasive medical devices, if they meet other Part A criteria for listing, will now be eligible for listing on PL. This recognises that if the device is no less clinically and cost-effective than an implantable device for treatment of a particular condition (disease or injury or disability), even if it achieves a clinical outcome by a different means, it should attract the same price compared with the implantable device intended to be used for a similar or the same purpose.

The emphasis is on health outcomes and efficient prices for the Australian public, and acknowledging that in some cases implantable and non-implantable devices are comparable and may, in some cases, be interchangeable technologies (e.g. in some cases a cardiac balloon or stent may be used for the same purpose and achieve the comparable outcome).

It is also proposed that the devices that are essential and specifically designed as a single-use aid for implanting a prosthesis, or are critical for maintaining ongoing-function of the surgically implanted prosthesis will also continue be eligible for listing on the PL.

There will be however **some exemptions** that include:

- **Devices intended for general purpose (general items)** that are intended to support a range of different types of surgical procedures and are either inserted into the body or assist other items that are inserted into the body (e.g. absorbable or not absorbable sutures (e.g. for soft tissue approximation), surgical staples, haemostatic agents, etc.).
- **Consumables,** the devices that are used and replaced regularly (removable sutures, needles, tubing, topical adhesives, and sealants for wound dressing)
- **Accessories,** the devices designed and intended by the manufacturer to always be used together with another implantable or surgically invasive device for therapy, to enable that device to be used as the manufacturer intended. Some of these devices (accessories) will no longer be separately funded through the PL, but instead it is anticipated that their cost will be bundled into the cost of the device they are intended to be used with or funded under a different funding mechanism).
  [These issues will further be considered as part of the revision of the current grouping scheme and the associated future consultation].

The **criterion that the device is to be at least, of similar clinical effectiveness and cost effectiveness** compared to alternative prostheses on the PL or alternative treatments will remain. It means that assessment of the comparative clinical effectiveness of prostheses and the proposed prices to inform decisions about reimbursement by private health insurers will continue.

Part B

In 2019, the Department commissioned a review of Part B of the Prostheses List. The Department will consult on possible changes resulting from that review separately.

Subject to any further changes proposed in any future consultation process, it is anticipated that Part B will continue to cover human tissue products that are substantially derived from human tissue where the tissue has been subject to processing or treatments, and whose supply [however described, including trade, sell, give or gift] is governed by state or territory law.

The existing criteria for listing (although not explicitly written) are taken that these products are implantable meaning that it is intended by the manufacturer to be, by surgical intervention, wholly introduced into the body of a human, and to remain in place after the procedure. It is taken that human tissue products are regulated as biological under the TG Act.

It is proposed these criteria will remain and will be prescribed in the Prostheses Rules. A separate discussion paper will explore the Part B issues that are proposed for amendment.

Part C

Part C will continue providing discretion for the Minister to list on the PL devices that do not meet the Part A criteria but where they may be required due to unmet clinical need or other exceptional circumstances and which have been assessed as being clinically effective and cost effective by MSAC.

It is proposed that Part C will continue, with the criteria for listing covering high cost and high clinical value devices that demonstrate:

- high and unmet clinical need and
- clinical and cost-effectiveness assessed by the MSAC and
- demonstrated cost saving to the health system in comparison to current treatments.

Some devices currently listed on Part C may be eligible for listing on Part A under the revised Part A listing criteria.

Guidance will be developed to assist in identifying products that will qualify for listing on Part C.

Impact – how the Prostheses List will change

Expanding Part A criteria for listing to the short-term or long-term surgically invasive medical devices for a specified therapy will result in devices such as cardiac ablation devices becoming eligible for listing on the PL Part A.

However, the exceptional circumstances provisions may still allow ablation mapping catheters to be listed on Part C if it is interpreted that these devices are used for diagnosis even though they are part of the ablation procedure.

General items, mostly listed in the General Miscellaneous Category of Part A, will be removed from the PL. The Government has an expectation that for those items removed insurers and private hospitals will reach an agreement on a market based alternative funding arrangement and one that does not involve out of pocket costs for the consumer.

There also will be clarity that consumables devices are not eligible for listing on PL.

Some devices that are accessories intended to be always supplied and used together with an implantable or surgically invasive device will no longer be separately funded through the PL. Instead it is anticipated that their cost will be bundled into the cost of the device they are intended to be used with or funded under a different funding mechanism.

This will be defined in the PHI legislation (the PHI Act and Prostheses Rules) and in the PL Guide.

Tables with general items identified for removal or retention on the PL are available at Attachment A.

Further tables are provided at Attachment B which test the proposed definition and criteria against a range of products.

It is proposed to remove the items in a staged way and align removal of the items with the regular updates to the PL. Comment is sought on the most appropriate timing and bundling.

Alignment with the TGA terminology

It is recognised that sponsors interact with the TGA and the PL processes regularly and often at the same time for the same products, although for different purposes. Alignment of terminology will assist in consistent interpretation of the status of the products, sponsors apply to be included in ARTG and listed on the PL.

As indicated earlier, the PL will include products used for therapy which are classified as medical devices and biologicals by TGA but will not include medicines or other therapeutic goods.

It is proposed that the meaning of a medical device, biological, accessory, implantable medical device, short-term or long-term, surgically invasive medical device, device for therapy, etc will be consistent with the definitions and terms used in the TG Act and respective regulations.

For example:

- medical device has the meaning given by section 41BD of the TG Act
- biologicals has the meaning given by section 32A of the TG Act
- accessory has the meaning given in section 3 of the TG Act
- implantable medical device or surgically invasive medical device have the meaning as defined in Dictionary of the *Therapeutic Goods (Medical Devices) Regulations 2002*
- short-term or long-term use mean the use defined in clause 1.1 of - Schedule 2 of the *Therapeutic Goods (Medical Devices) Regulations 2002*.

The name of the Prostheses List

There have been discussions about whether the name ‘Prostheses List’ accurately reflects the products eligible for listing, or if it is misleading and should be changed. In common English, many people understand a prosthesis as being prosthetic limbs, but these products are excluded from being eligible for listing on PL.

As part of the reforms, there is an opportunity to revise the name of the PL to provide improved clarity and transparency.

It is important to note that this consultation paper has been prepared to reflect the government’s decision taken in the 2021-22 Budget.

What we invite you to do

Please consider the questions below and provide your responses, and any other comments related to the matter outlined in this consultation paper.

This consultation paper will be open for four weeks until **17 September 2021**. The Department intends to convene a clinical advisory group to assist in analysing the comments received and finalising the items to be removed. A final list of items for removal will be announced in November 2021.

Definition & Scope

1. Is the proposed approach to the definition of a kind of prosthesis flexible enough to anticipate future technologies while providing sufficient clarity on the scope of PL?
2. Does aligning terms with established terms used by TGA (such as medical devices and biologicals) improve clarity?

Criteria

3. Are the proposed listing criteria for Part A fit-for-purpose? If not, what changes are needed?
4. Should the scope of products eligible for listing on Part B remain unchanged?
5. Should the PL retain an option for the Minister to list items in exceptional circumstances on Part C?
6. Are there any other exceptional circumstances factors that Part C should accommodate?
7. Please consider the tables at Attachment B and explain which products meet the future criteria for listing and the reasons why?

Name

8. Should the name of the list be modernised and, if so, what should it be called?

Consequence of Changes

9. Does the list of items at Attachment A flagged for inclusion and removal accurately reflect the proposed future criteria for listing?
10. The removal of items identified at Attachment A is scheduled to commence from February 2022. If a decision is taken to remove these items in tranches, is there a logical bundling of the items at Attachment A that would make staged implementation over time possible? Is the proposed staged removal aligned with PL updates workable? What is the most appropriate timing?

How to submit

Please submit your feedback via the Consultation Hub.

References

1. 2021-22 Budget Fact sheet - Private Health Insurance – Modernising and Improving the Private Health Insurance Prostheses List, https://www.health.gov.au/resources/publications/private-health-insurance-modernising-and-improving-the-private-health-insurance-prostheses-list
2. Consultation Paper: Options for reforms and improvements to the Prostheses List, released 18 December 2020, https://consultations.health.gov.au/technology-assessment-access-division/prostheses-list-reform-options/
3. Review of the General Miscellaneous Category of the Prostheses List Report, Published 3 December 2020, https://www.health.gov.au/resources/publications/review-of-the-general-miscellaneous-category-of-the-prostheses-list-report
4. *Private Health Insurance Act 2007,* https://www.legislation.gov.au/Series/C2007A00031
5. *Private Health Insurance (Prostheses) Rules (No. 2) 2021,* https://www.legislation.gov.au/Details/F2021L00785
6. Prostheses List - Guide to listing and setting benefits for prostheses, https://www.health.gov.au/resources/publications/prostheses-list-guide
7. Therapeutic Goods Act 1989, https://www.legislation.gov.au/Series/C2004A03952
8. Therapeutic Goods (Medical Devices) Regulations 2002, https://www.legislation.gov.au/Series/F2002B00237
9. Private Health Insurance (Prostheses Application and Listing Fee) Rules 2018, https://www.legislation.gov.au/Series/F2018L01323

ATTACHMENT A

Prostheses List groups proposed to be removed, taking into account the EY report

Alternative funding arrangements are currently being developed that reflect the items identified for removal.

Table 1: General Miscellaneous Items Proposed for Removal and 2018-19 Prices Paid

Part A – General Miscellaneous Category	2018-19 ($)
03.02 - Drug Delivery Devices (except 03.02.01 - Infusion Ports and 03.02.06 Pharmaceutical beads (embolization systems)	12,168,349
03.03 - Enteral Tubes	251,232
03.05 - Haemostatic Devices	38,016,106
03.08 - Closure Devices, specifically:	
03.08.01 - Adhesion Barriers	4,717,235
03.08.02 - Internal Adhesives	44,237,662
03.08.03 - Ligating Devices	28,168,640
03.08.04 - Staples & Tackers	98,831,602
03.08.11 - Dynamic Wound Closure Devices	6,720

Source: Hospital Casemix Protocol 1 (HCP1), Department of Health.

Table 2: Other Part A Items Proposed for Removal and 2018-19 Prices Paid

Part A – Other Devices	2018-19 ($)
01.03 - Intraocular fluids	14,589,525
04.02.05 - Liquid sealants large	309,520
04.02.06 - Liquid sealants	1,519,422
04.02.07 - Repair, Self-Adhesive Membrane Sealant, Small (≤10cm²)	. .
04.02.08 - Repair, Self-Adhesive Membrane Sealant, Medium (>10 to 50cm²)	. .
10.07.01 - Arterial closure devices	11,207,091

. . No data

Source: Hospital Casemix Protocol 1 (HCP1), Department of Health.

Table 3: Part A - General Miscellaneous Items Proposed to be Retained and 2018-19 Prices Paid

Part A – General Miscellaneous Category	2018-19 ($)
03.01 Brachytherapy	6,461,604
03.02.01 - Infusion Ports	280,595
03.02.06 Pharmaceutical beads (embolization systems)	115,624
03.04 Gastric bands	4,227,671
03.06 Luminal stents	5,113,563
03.07 Pulmonary/Peritoneal catheters	1,967,631
03.08 Closure Devices, specifically	
03.08.05 mesh	3,745,722
03.08.06 mesh	7,377,241
03.08.07 mesh	2,953,583
03.08.08 mesh	110,369
03.08.09 plugs	1,146,850
03.08.10 - Anastomosis Clip	35,517

Source: Hospital Casemix Protocol 1 (HCP1), Department of Health.

ATTACHMENT B

Examples of products that may be eligible or not eligible for listing on PL under the revised criteria for listing

Table 4: Examples of products to test the definition and listing criteria

Kinds of products	Therapy/diagnosis Implantable/Surgically invasive/Not invasive	Part A/ Part B/ Part C
Femur – Proximal	Human tissue product/ Therapy/Implantable	Part B
Hip Femoral Stem	Medical device/Therapy/Implantable	Part A
Knee hinge ancillary implants (augments, plates, wedges, etc)	Medical device/Therapy/Implantable	Part A
Cardiac pacemaker	Medical device/Therapy/Implantable	Part A
Cardiac leads for pacemakers		
Cardiac ablation catheter	Medical device/Therapy/Surgically invasive	Part A (?)
Mapping catheter for catheter cardiac ablation		
Other cardiac ablation devices		
Cardiac remote monitor (i.e. the bedside monitor)	Medical device/Therapy/Not invasive	Part C
Insulin pump	Medical device/Therapy/Not invasive	Part C
Surgical guide or biomodel	Medical device/Therapy/Surgically invasive	Part A (?)
Intraocular dye	Medical device/Therapy/Surgically invasive	Part A (?)
Coronary pressure wire	Medical device/Diagnosis-measurement/ Surgically invasive	Part C (?)
Drug eluting vascular balloon catheters	Medical device/Therapy/Surgically invasive	Part A (?)
Mechanical thrombectomy catheter and stent retriever	Medical device/Therapy/Surgically invasive	Part A (?)
Microcatheter (small diameter catheter)	Medical device/Therapy/Surgically invasive	Part A (?)
Ophthalmology microcatheter	Medical device/Therapy/Surgically invasive	Part A (?)

Table 5: Examples of systems that may be considered as a kind of prosthesis

Kinds of products	System / kit (Yes/No)
Implantable neurostimulation system (including neurostimulator, patient programmer, remote control, tools for implanting, leads)	Yes (?)
Implantable bone conduction hearing systems (including implant, abutments, fixtures, couplings)	Yes (?)
Active Middle Ear Hearing Systems (including implant, coupler)	Yes (?)
Intrathecal Drug Delivery Device (including implantable pump, patient programmer, implantation tools, refill kits)	Yes (?)
Hydrocephalus System (including valve, catheters, reservoirs, shunts)	Yes (?)
Inflatable Urinary Incontinence Prostheses (including pump, cuff, balloon, accessories)	Yes (?)
Penile Prostheses Systems – Inflatable Three Component (including pump, cylinder, reservoir, controller)	Yes (?)
Dental implants (including implant, abutment [healing and permanent], screws, cover screw/cap)	Yes (?)
Spinal fusion cage system (including cage, screws, plates)	Yes (?)