Response ID ANON-3NHQ-DDGP-S

Submitted to Proposed refinements to the regulation of personalised medical devices
Submitted on 2021-07-14 19:07:30

Introduction

1 What is your name?

Name:
[redacted]

2 What is your work title?

Work title:
[redacted]

3 What is your email address?

Email:
[redacted]

4 What is your company/organisation?

Organisation:
Prosthetic Art Technology Pty Ltd

5 What is your company/organisation address?

Please provide the business address of your company or organisation.:

2/2 High St,
Alstonville NSW
2477

6 Which industry do you work in, or represent?

Please state the industry that you work in, or are representing in your submission.:
Anapalstology (custom face and body prostheses)

7 Are you responding:

As an individual

Exclusion

8 Do you agree with the rationale for the proposed exclusion of products?

Yes

If you answered 'no' to the above question, why do you disagree with the rationale for the proposed exclusion of the products listed?:

9 Are the risks posed by the products adequately managed if they are excluded from regulation by the TGA?

Yes

Please explain your response, including by providing examples that illustrate and/or support your position.:

I believe that risks products pose will be adequately managed through ACCC and appropriate consumer protection laws.

10 Are there further products that meet the principles proposed for exclusion? What are they and why should they be excluded?

Ensure your answer directly addresses (1) why the products pose no, or insignificant, levels of risk or (2) why the product does not meet the definition of a medical device. :

Further products are listed below where I believe they would meet the principles proposed for exclusion as they meet the definition of a medical device, or an accessory to a medical device, or meet the definition of a medical device but are predominantly used for cosmetic purposes and do not present a risk of harm.

1. Custom made cosmetic covers for upper and lower limb prostheses (low risk cosmetic accessory to a medical device)

2. Custom silicone liners for functional upper or lower limb prosthesis, manufactured according to design prescription of prosthetist/orthotist. (Low risk accessory to a medical device)

3. Virtual impressions of a patient's anatomy, software and 3D printed models when being used in the manufacture of Class I non-sterile, non-measuring patient-matched medical devices such as facial prostheses (low risk of harm correlating to the classification of the device being manufactured).

4. External removable prosthetics for the face and body that have some passive functional capacity, but also have a high psychosocial value because of the cosmetic function, e.g., nipples, scar divots, fingers, toes, ear, eye, and nose prostheses. Most of these prostheses are very low risk, however depending on user requirements and specialist prescription, some of these prosthetic types may involve connection to other medical devices such as bone anchored implants (e.g. implant retained facial and finger prosthesis), they may be used as a protective covering (e.g. when a hole forms post surgically in the skin that directly communicates with the craniofacial sinuses below, or to help humidify the nasal cavity when the nose has been removed), or may have a connection to a dental prosthesis (e.g. if there is a dental obturator prosthesis that communicates to an open orbital cavity, an eye prosthesis including prosthetic eyelids and surrounding skin may connect through the open orbital cavity to the dental obturator to be held into position, this would be supplied in collaboration with a prosthodontist). In these types of more complex instances, it may be more suitable for these devices to be considered for exemption rather than exclusion.

Exemption

11 Do you agree with the rationale for the proposed exemption of Class I non-sterile, non-measuring patient-matched devices when produced under the circumstances listed in the consultation paper?

Yes

If you answered 'no' to the above question, please explain why it is that you disagree with the rationale for the proposed exemption of Class I non-sterile, non-measuring patient-matched medical devices?:

I welcome TGA's proposed the regulation exemption of Class I non-sterile, non-measuring patient-matched devices where it can be demonstrated the risks associated with the manufacture and use of the device can be adequately managed. If the device is manufactured by a trained, accredited professional; or other third-party mechanisms of oversight are in place that are suitable to manage the low risk that may be posed by the device. I welcome the proposed exemptions when a Class I non-sterile, non-measuring patient-matched device is manufactured in an accredited healthcare facility or by a provider who has been registered with the National Disability Insurance Scheme as this proposal will significantly reduce unnecessary burden on healthcare professionals.

12 Can the risks posed by Class I non-sterile, non-measuring patient-matched medical devices when produced under the circumstances listed in the consultation paper be adequately managed if they are exempted from inclusion in the ARTG?

Yes

Please explain your response, including by providing examples that illustrate and/or support your position.:

See next answer

13 Are there further circumstances where Class I non-sterile, non-measuring patient-matched devices could be exempt? If so, what measures are in place to manage the risks associated with the devices?

Ensure your answer directly addresses the specific circumstances that are in place (such as qualifications, accreditation, certification, etc) to ensure that the risks associated with the manufacture of the devices have been managed and the Australian regulatory requirements for medical devices have been met before they are supplied.:

I would like to propose further circumstances below where Class I non-sterile, non-measuring patient-matched devices could be exempt.

1. Profession: Anaplastologist
Devices:
- Facial prostheses: also known as epitheses* or extra-oral maxillofacial prosthetics, include auricular, nasal, mid-facial, orbital (including ocular), upper facial, hemi-facial, partial facial, nasal septal and other areas of the head and neck, but exclude intra-oral prostheses (1). These are removable prostheses that are usually highly realistic in appearance, and may be attached to the body via spectacles, adhesive, or bone anchored implants.
* International nomenclature for extraoral facial prostheses

- Somatic prostheses: include fingers, thumbs, partial hands, hands, breasts, toes,
cosmetic partial feet and other areas of the body, but exclude prosthetic devices for weight-bearing anatomy.1 These are removable prostheses that are usually highly realistic in appearance, and may be attached via passive vacuum (suction retained), adhesive, or bone anchored implants.

Australian Governance:
Anaplastology is a small and currently self-regulated profession. The field collaborates with dental, surgical, psychological, prosthetic/orthotic, and other rehabilitation specialties to provide service but sits well outside those specialties in terms of skill set and job requirements. Anaplastologists do not require dental qualifications as they work outside the mouth focussing on highly detailed reconstruction of the face and body, nor do they require prosthetic/orthotic certification because they are not providing biomechanical weight bearing prostheses. Given the small number of providers within Australia there is currently no existing Australian association for the profession. Several international associations are used for guidance to the profession:

• The Institute for Maxillofacial Prosthetists and Technologists (IMPT) UK Based
International Membership given only on approval from the IMPT following proof of membership qualification and recommendation from a member.
• The International Anaplastology Association (IAA)
Active Membership available for those actively participating in the association.

Historically in Australia a facial prosthetist would be trained on the job in a facial prosthetic unit, however, to keep up with rapid technological advancements and world standard clinical practices, overseas based, profession-specific post-grad qualifications are now sought for Australian providers increasing the quality and availability of service provision across the country. There is precedent of these qualifications being sought and accepted at various tertiary and quaternary care hospital departments in Australia, and for an Anaplastologist to be accepted as a registered NDIS provider for the custom prosthetics registration group for providing facial prosthetics.

Risk management

Facial prostheses are required to manufactured safely, considering infection control guidelines, materials safety, and patient medical status, often on referral and specification from a medical specialist. Prostheses manufactured and provided incorrectly and without suitable training can create infection control risk and risk of damage to patient tissues such as skin break down or failure of bone anchored implants (2). Risk management for these Class I non-sterile, non-measuring patient-matched prosthetic devices prosthetic types is managed by:

o Manufacture within a healthcare facility accredited against the National Safety and Quality Health Service (NSQHS) Standards by a body recognised by the Australian Commission on Safety and Quality in Health Care (ASCQHC); or
o By a provider who has been registered with the National Disability Insurance Scheme Quality and Safeguards Commission (NDISQSC), and the scope of their registration encompasses the patient-matched medical devices that they are producing.
(I note that there may be some long term Anaplstologists in private practice in Australia that will not be working in an accredited healthcare facility, nor would be registered with the NDIS.)

Example 1
Custom made orbital prosthesis – Implant Retained
- Patient Bob has had his eye and surrounding soft tissue removed to treat an invasive cancer. He is left with a deep skin covered cavity where his eye was and has been prescribed an implant retained orbital prosthesis by his rehabilitation team as the most suitable form of reconstruction. Bob's reconstructive team surgically place some dental implants that protrude through the skin that the removable prosthesis will attach to.
- The anaplastolgist may assist prior to surgery in the planning process by visualising the prosthetic position (physically on a physical model or virtually on a virtual model) for the surgical team so the surgical specialists can then plan implant locations that will work according to the patients anatomy, and will also be able to be hidden inside the prosthesis.
- After surgery and healing Bob is referred to the anaplastologist to manufacture an orbital prosthesis that will attach to the implants via magnets or clips. This prosthesis is manufactured over a series of consultations with the anaplastologist at either a hospital outpatient clinic at a healthcare facility accredited against the NSQHS Standards by a body recognised by the ASCQHC or
- At a private anaplastology practice by an anaplastologist who has been registered with the NDISQSC for the custom prosthetics registration group for providing facial prosthetics.

References:
1. Association IA. Clinical Anaplastology Guidelines 2000 [Available from: https://inaa.memberclicks.net/assets/PDFs/Clinical%20Anaplastology%20Guidelines%20-%20International%20Anaplastology%20Association%202020.pdf.
2. Aydin C, Karakoca S, Yilmaz H, Yilmaz C. Implant-retained auricular prostheses: an assessment of implant success and prosthetic complications. Int J Prosthodont. 2008;21(3):241-4.

Alternative conformity assessment procedures

14 Do you agree with the rationale for the proposed alternative conformity assessment procedures for Class IIa patient-matched medical devices when produced under the circumstances listed in the consultation paper?

Yes

If you answered 'no' to the above question, please explain why you disagree with the rationale for the proposed alternative conformity assessment procedures for Class IIa patient-matched medical devices?:

15 Do you agree that the risks associated with the Class IIa patient-matched medical devices when produced under the circumstances listed in the consultation paper could be adequately managed through the proposed alternative conformity assessment procedure?

Not Answered

Please explain your response, including by providing examples that illustrate and/or support your position.:

No Comment

16 Are there further circumstances where an alternative conformity assessment procedure for Class IIa patient-matched devices would be appropriate?

Please ensure that your answer directly addresses what measures are in place to manage the risks associated with the devices.:

No comment

17 Are there any Class IIa patient-matched medical devices that should not be subject to an alternative conformity assessment procedure? What are they, and why not?

Please outline your reasoning.:

Yes, as described above virtual and physical models, and software used during the manufacture of Class I non-sterile, non-measuring patient-matched prosthetic devices should not require higher regulation than the device the software and hardware is being used to produce.
For example:
o To manufacture an ear prosthesis an anaplastologist would traditionally use physical impressions and physical models of the patient to create anatomical forms of the patients affected and non affected ears. The prosthetic ear would be a freehand mirrored image of the patients non-affected ear that was sculpted by hand, the result would be entirely dependent on the anaplstologsts artistic sculpting skill and is extremely laborious.
o Now with the use of scanning and 3D computer modelling and printing, the patients unaffected ear can be easily mirrored and printed to create an extremely accurate anatomical model that can then be duplicated and finished in the traditional manner to help create a more anatomically correct ear prosthesis. This process is fast, and low risk, creating a better eventual prosthetic result than if it were done by freehand sculpting.
o Classing these types of virtual and physical models as IIa will serve to stop the adoption of 3D technologies being applied in low-risk devices such as facial prostheses.

Alternative approaches we should consider

18 Are there alternative mechanisms for minimising the regulatory burden for patient-matched medical devices without compromising patient health and safety that you would like to propose?

If applicable, please write your response in the text box below.:

No

Required final step - Publishing my response

19 Do you consent to the Department collecting the information requested in Citizen Space about you, including any sensitive information, for the purposes of this consultation?

I consent

20 I consent to the submission made by me being published on the Department’s website, and accessible to the public, including persons overseas, in accordance with the following preference:

Publish response, without my name but including my organisation's name

21 If there are specific answers you have provided that you do not wish to be published, please indicate these below.

Please state below any specific questions that you do not wish to have your answers to published.:

22 May we contact you for further information or to seek feedback about how the consultation was undertaken?

Yes

23 By making a submission, I acknowledge that:

I acknowledge the above