Response ID ANON-3NHQ-DDKH-N

Submitted to Proposed refinements to the regulation of personalised medical devices
Submitted on 2021-07-13 13:34:35

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:
[redacted]

5 What is your company/organisation address?

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

[redacted]

6 Which industry do you work in, or represent?

Please state the industry that you work in, or are representing in your submission.:
[redacted]

7 Are you responding:

On behalf of an organisation

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.:

Custom-made prosthesis/orthosis meet the classification of Class 1 non-sterile, non- measuring devices. They are therefore defined as being low risk, with the potential to cause harm or injury being minimal, if regulatory obligations are fulfilled by the manufacturer.

However, clear delineation needs to be made when considering a prosthesis which is attached via osseointegration. Osseointegration allows the direct attachment of an external prosthesis to the skeleton through the surgical implantation of an intramedullary device (not a class 1 device). Only the external elements of the prosthesis would be classified as patient matched class 1 non-sterile devices.

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. :

No, all custom-made prosthesis/orthosis which meet the regulatory obligations for class 1 non-sterile, non-measuring devices including compliance with the essential principles and adverse event reporting requirements should be considered for 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?:

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.:

There are numerous regulatory mechanisms currently in place, which have the capacity to allow for adequate monitoring and reporting of manufactures within the Prosthetics and Orthotics Profession, particularly in a clinical setting governed by [redacted].
Prosthetists/Orthotists within [redacted] must hold a professional qualification, minimum 3 years tertiary degree. [redacted] employed Prosthetist/Orthotists must also meet the requirements for registration/membership with the Australian Orthotic and Prosthetic Association, the current relevant national body.
Working within [redacted], employees are required to comply with Australian and state legislation and at a health district level, policies, procedures, and Work Unit Guidelines. Conformity assessment procedures, as defined by the TGA are considered mandatory.
Employees of [redacted] are required to routinely complete online and onsite competency training and supervision. A supervision framework exists to support employees.
[redacted] and [redacted] employees are governed by the NSQHS standards as an accredited organisation. As a result, [redacted] is subject to regular auditing to ensure accreditation is maintained.
[redacted] provides a state-wide reporting system [redacted] to ensure the identification, reporting and subsequent management of clinical and workplace incident, consumer feedback and risk analysis. Risk analysis of items, materials including material data sheets, and patient risks are identified, and a follow-up review structure exists.

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.:

No

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?

No

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?:

Should remain a requirement to be included on the ARTG due to the higher level of risk posed ie risk of infection due to penetration of the skin.

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?

No

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

As above

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

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.:

No

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.:

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 or my organisation's name (anonymously)

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.:
no details regarding name

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