Response ID ANON-3NHQ-DDS5-A

Submitted to Proposed refinements to the regulation of personalised medical devices
Submitted on 2021-07-14 11:19:10

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:
Wener Sauer Smile Design

5 What is your company/organisation address?

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

Level 1
15 Mallon St
Bowen Hills
QLD 4006

6 Which industry do you work in, or represent?

Please state the industry that you work in, or are representing in your submission.:
Dental Laboratory

7 Are you responding:

On behalf of an organisation

Exclusion

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

Not Answered

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?

Not Answered

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

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. :

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?

Not Answered

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?

Not Answered

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

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.:

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?

Yes

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

From the perspective of a Dental Laboratory that has suitably qualified Dental technicians manufacturing the prosthesis:
It will be enough that this combination of a registered Laboratory with OHPA, qualified dental technicians (although the industry is de-registered) and the prescription of a Dentist (qualified health practitioner) ensures the standard of each patient matched device produced is high and suitable clinically, functionally and aesthetically.
By removing the burden from the Dental Laboratory (manufacturer) to have a regulatory body assess and certify the laboratory, it makes it a lot simpler to produce the class IIa devices by being able to select the most suitable materials and techniques for each device. Being locked into a fixed system that requires you to use just the materials and techniques of just one company (eg Dental supplier like [redacted]) will not cover all patient matched class IIa medical devices.
We are an industry leader in the patient matched class IIa medical devices called All on 4 (implant supported full arch restoration replacing a full arch of failing dentition) and we can attest that there is not one size fits all restoration for this. There are many variables that can be used within the patient matched device. For example, there is monolithic zirconia All on 4. zirconia over Ti bar All on 4 , temporary All on 4 in pekkton/pmma combination (for immediately after surgery) and more. We use photogrammetry to replace analogue impression taking for the highest degree of accuracy. Having some degree of flexibility to create our own system without excessive regulatory burden is of benefit to the end user, the patient. This way the patient will end up withe the best possible device manufactured in the best possible materials and techniques and created by the professional standards of the Dentist, Laboratory and Technician combination.
We support this alternative assessment conformity as the regulatory burden on the current proposal would be too high for a lot of laboratories and they would lock themselves into a system by a particular dental supply company who is taking on the majority of the regulatory burden for them. We believe by locking yourself into one system, it is too rigid to produce the ideal patient matched device for the patient circumstances each and every time. It also discourages innovation and further development/improvement as the particular system that may be chosen, might not keep up with the latest techniques and technologies.

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, covered all above

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.:

Not for our circumstances

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 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