Response ID ANON-3NHQ-DDCR-Q

Submitted to Proposed refinements to the regulation of personalised medical devices
Submitted on 2021-07-14 10:37:30

Introduction

1 What is your name?

Name:
[redacted]

2 What is your work title?

Work title:
DENTAL LAB OWNER

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.:
DENTAL LABORATORY ORTHODONTIC

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.:

In the dental industry patient matched medical devices are designed and approved by a orthodontist (post grad degree) the orthodontist checks the quality and safety of the device supplied. Orthodontist are very thorough in there scrutiny of medical devices.
All medical devices should only be manufactured under the scrutiny of a qualified dental technician and approved for use by a registered orthodontist.

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. :

All dental patient matched medical devices should be excluded from as existing regulation has already been provided by professional bodies such as the ADA and the ASOand the scrutiny of the orthodontist or dentist.

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.:

all patient matched medical devices are designed ,prescribed and scrutinised prior tone given to the patient by the orthodontist.

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.:

I can only speak for orthodontic laboratories. Orthodontic laboroties combined with the orthodontist already have procedures in place to mitigate problems that could arise with medical devices .
1 on receiving the mould of the patients teeth and prescription slip which has the design of the appliance which has been done for the individual patient the lab checks the mould for faults and if the laboratory deems there is a fault with the mould it is sent back to the orthodontist to be re-taken.
2 once the medical device is made by the laboratory it is checked by the dental technician to make sure the device matches the prescription issued by the orthodontist , once its checked and all is correct it is returned to the orthodontist.
3 when the orthodontist receives the device the orthodontist checks the appliance once again to make sure every detail is correct and if the orthodontist wants something changed on the device it is sent back to the laboratory to be adjusted.
3 Once the orthodontist is happy with the device it is placed in the patients mouth by the orthodontist and the patient given instructions on how to use the the device and given a after hours phone number to call if the patient needs . Each device instructions is individual to the particular patient which is pre determined by the orthodontist,
4 during the devices use it is checked and maintained by the orthodontist to make sure the the device is being maintained by the patient, if instructions of use need to be changed as the treatment goes forward, to check if the treatment is finished and the device can be removed and for any problems that could occur.
5 devices are checked periodically by the orthodontist , this can be monthly or a time determined by the orthodontist, patients are given instructions to call the orthodontist if they are concerns and are seen very quickly by the orthodontist.
6 except for fixed retainers (a small wire which is bonded onto the palatal surface of the anterior teeth) no orthodontic device is left permanently in the mouth. and because of the checks by the orthodontist and instructions given to the patient very rarely issues arise and if they do the orthodontist will remove the device or determine the best cause of action.
7 All devices should be made from tga approved components and assembled by a qualified dental technician only to the prescription details.

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.:

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.:

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.:

1 all devices constructed should be made only by a qualified dental technician.
2 only tga approved components used.
3 devices supplied to patients should be made in australia to maintain the high standards of devices .
4 dental labs registered with the Australian dental association.

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.:

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