Response ID ANON-3NHQ-DDDG-D

Submitted to Proposed refinements to the regulation of personalised medical devices
Submitted on 2021-06-21 17:06:51

Introduction

1 What is your name?

Name:
George Kalomallos

2 What is your work title?

Work title:
Director

3 What is your email address?

Email:
[redacted]

4 What is your company/organisation?

Organisation:
ComfiTech Orthotic Laboratory Pty Ltd

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.:
Victoria

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.:

Yes they are as in the case of foot orthotics the podiatrist or Allied health professional prescribes the orthotic for the patient.
The manufacturer simply manufactures this device according to the prescribed design. These designs are CAD computer aided and locked to that patient.
There is a specified order number and details of the design that a CAM Computer aided Manufacturing device then produces.
The manufacturing process doesn't interfere with the prescription provided for the design this is driven and locked in by the podiatrist and their prescription in the system.
The Product ordering system including the CAD and CAM have an ordering tracing system in place. The unique order number matched to the patient, the prescription, material to be used, design styles, size and shape, including length and width, densities of material to be used all from a selection criteria checklist.
The orthotic Insoles are designed to improve the health of the patient. If an orthotic designed by a podiatrist is eg too aggressive or not too confirmative the patient will feel uncomo0ftable and wont wear it. The adverse affects of any designed orthotics by the health professional not serving the desired health outcome are addressed immediately as these are easily adjusted to ensure levels of comfort are achieved. Adjustments are usually needed by the podiatrist in order to effectively fit the orthotics is shoes, these adjustments are handled by the Podiatrist and ion turn any feeling of discomfort is handled at the time of fitting.

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. :

Products Such as AFO's Ankle and foot orthosis external devices other than orthotic insoles. They are generally fitted when custom made, and adjustments are made during fitting. They are of minimal risk as they are non intrusive and externally used. Any level of discomfort is picked up very early by the patients and or professional fitting it.
These devices are tracked in the same was through the prescription and design process.

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.:

Yes they can. As long as there is a sound product ordering process in place that can link back to the matched device criteria then there is an end to end trail or actions.
The devices don't pierce the skin therefore the adverse risks are minimal and can be addressed immediately.

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.:

NA

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.:

These devices are hinged to the body and can have sensory and skin affects to the patient. They require a trained professionals to have them removed and or adjusted. Having a elf assessment process would suffice including the manufacturing and technical data as record keeping. The manufacturing facilities and examples listed would have enough control process in place to ensure conformity to manufacturing

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.:

NA

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.:

NA

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.:

A degree of logic and care should be given when considering these changes. In the case of Foot Orthotics (insoles) patients can and do buy off the shelf precast orthotics that many times cause more issues than resolution.
When considering a customer made Foot Orthotic (Insole) the patient has a direct relationship with their health professional ensuring the prescription is tailored to their condition thus assisting to improve their overall wellbeing.
The manufacturing process via an end to end order management system and CAD CAM system ensures minimal risk in incorrect production.
The health professional at the time of fitting makes all the necessary adjustments to ensure the Foot orthotic fits well and the the patient experiences immediate benefit.
There is no skin penetration or insertion of any type.

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, including both my name and 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.:
NO

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