Response ID ANON-A5FQ-NE2Q-3

Submitted to Notification form: Reclassification of spinal implantable medical devices
Submitted on 2022-03-15 00:44:33

About the submitter

1 What is your name?

Name:
FH Industrie

2 What is your email address?

email:
s22 @fh-industrie.com

Please confirm your email address:
s22 @fh-industrie.com

3 Which of the following best describes your role in relation to the medical device for which this notification is being submitted?

Manufacturer

4 What is the name of the sponsor of this medical device?

Sponsor name:
Orthotech Pty Ltd

ARTG 1

1 Please mention the ARTG number:

ARTG Number: 1:
205414

2 What is the GMDN code for this kind of medical device?

GMDN Code:
48164

3 What is the current classification of this kind of medical device?

Class IIb

4 What will be the new classification of this kind of medical device?

Class III

5 Please provide the following:

The number of UPIs that are supplied under this ARTG:
1

UPI-1 and variants:
UPI: CP-ESP DISC PROSTHESIS / CEMENTLESS, and variants: SIZE: S1 (13x15) H5, SIZE: S1 (13x15) H6, SIZE: S1 (13x15) H7, SIZE: S2 (14x17) H5, SIZE: S2 (14x17) H6, SIZE: S2 (14x17) H7, SIZE: S3 (15x20) H5, SIZE: S3 (15x20) H6, SIZE: S3 (15x20) H7.

UPI-2 and variants:

UPI-3 and variants:

UPI-4 and variants:

UPI-5 and variants:

UPI-6 and variants:

UPI-7 and variants:

UPI-8 and variants:

UPI-9 and variants:

UPI-10 and variants:

6 Please specify the number of devices supplied in Australia, in 2019, for each UPI.

UPI-1 and variants:
221

UPI-2 and variants:

UPI-3 and variants:

UPI-4 and variants:

UPI-5 and variants:

UPI-6 and variants:

UPI-7 and variants:

UPI-8 and variants:

UPI-9 and variants:

UPI-10 and variants:

7 Please specify the number of devices supplied in Australia, in 2020, for each UPI.

UPI-1 and variants:
170

UPI-2 and variants:

UPI-3 and variants:

UPI-4 and variants:

UPI-5 and variants:

UPI-6 and variants:

UPI-7 and variants:

UPI-8 and variants:

UPI-9 and variants:

UPI-10 and variants:

8 Please select the most suitable option for each UPI.

UPIs planning to reclassify - UPI-1 and variants:
Planning to reclassify

UPIs planning to reclassify - UPI-2 and variants:

UPIs planning to reclassify - UPI-3 and variants:

UPIs planning to reclassify - UPI-4 and variants:

UPIs planning to reclassify - UPI-5 and variants:

UPIs planning to reclassify - UPI-6 and variants:

UPIs planning to reclassify - UPI-7 and variants:

UPIs planning to reclassify - UPI-8 and variants:

UPIs planning to reclassify - UPI-9 and variants:

UPIs planning to reclassify - UPI-10 and variants:

9 Please confirm if you will be submitting an application for your device to be included in the ARTG as a Class III medical device before 1 November 2024.

Yes, will be submitting an application for inclusion

10 Will you require a TGA conformity assessment for your device(s) to be included in the ARTG as a Class III medical device?

Yes

Please specify the number of UPIs that will require TGA conformity assessment:
1

ARTG 2

1 Please mention the ARTG number:

ARTG Number: 2:
181919

2 What is the GMDN code for this kind of medical device?

GMDN Code:
48165

3 What is the current classification of this kind of medical device?

Class IIb

4 What will be the new classification of this kind of medical device?

Class III

5 Please provide the following:

The number of UPIs that are supplied under this ARTG:
1

UPI-1 and variants:
UPI-1 : LP-ESP DISC PROSTHESIS / CEMENTLESS and variants : SIZE : 7° - H10mm, SIZE : 7° - H12mm, SIZE : 9° - H10mm, SIZE : 9° - H12mm, SIZE : 11° - H10mm, SIZE : 11° - H12mm.

UPI-2 and variants:

UPI-3 and variants:

UPI-4 and variants:

UPI-5 and variants:

UPI-6 and variants:

UPI-7 and variants:

UPI-8 and variants:

UPI-9 and variants:

UPI-10 and variants:

6 Please specify the number of devices supplied in Australia, in 2019, for each UPI.

UPI-1 and variants:
434

UPI-2 and variants:

UPI-3 and variants:

UPI-4 and variants:

UPI-5 and variants:

UPI-6 and variants:

UPI-7 and variants:

UPI-8 and variants:

UPI-9 and variants:

UPI-10 and variants:

7 Please specify the number of devices supplied in Australia, in 2020, for each UPI.

UPI-1 and variants:
407

UPI-2 and variants:

UPI-3 and variants:

UPI-4 and variants:

UPI-5 and variants:

UPI-6 and variants:

UPI-7 and variants:

UPI-8 and variants:

UPI-9 and variants:

UPI-10 and variants:

8 Please select the most suitable option for each UPI.

UPIs planning to reclassify - UPI-1 and variants:
Planning to reclassify

UPIs planning to reclassify - UPI-2 and variants:

UPIs planning to reclassify - UPI-3 and variants:

UPIs planning to reclassify - UPI-4 and variants:

UPIs planning to reclassify - UPI-5 and variants:

UPIs planning to reclassify - UPI-6 and variants:

UPIs planning to reclassify - UPI-7 and variants:

UPIs planning to reclassify - UPI-8 and variants:

UPIs planning to reclassify - UPI-9 and variants:

UPIs planning to reclassify - UPI-10 and variants:

9 Please confirm if you will be submitting an application for your device to be included in the ARTG as a Class III medical device before 1 November 2024.

Yes, will be submitting an application for inclusion

10 Will you require a TGA conformity assessment for your device(s) to be included in the ARTG as a Class III medical device?

Yes

Please specify the number of UPIs that will require TGA conformity assessment:
1

Declaration

1 I declare that all information provided in this form is true and correct at the time of submission. Important note: Providing information that is false or misleading to a Commonwealth entity or in connection with a Commonwealth law is a serious offence subject to criminal penalties under the Criminal Code Act 1995.

Yes