Medical Device Application

Class 1
Status : Approved

Application Change history

Application Progress Date	
Date received:	17/08/2016
Review Information	
Review flag:	
Auto review required:	No

ARTG & Product ID	
ARTG ID	279238
Product ID	555243

Application Details	
Application identifier:	DV-2016-DA-10185-1
Sponsor's own reference:	s 47(1)(b) [redacted]
Application for:	Medical Device - Included
Will you be applying for listing of this product or procedure in the Medicare Benefit Schedule (MBS)?	○ Yes ○ No
Will you be applying for listing of this product on the Prosthesis List?	○ Yes ○ No
Will you be applying for listing of this product on the Co-dependent or hybrid technology application list?	○ Yes ○ No
Cancel ARTG - product:	

Sponsor Details	
Agent name:	Emergo Asia Pacific Pty Ltd T/a Emergo Australia
Sponsor name:	Emergo Asia Pacific Pty Ltd T/a Emergo Australia
Contact details:	s 22(1) [redacted]
Contact email:	[redacted]

Class Details	
Class:	Class 1
Intended purpose:	The online assessment within the SkinVision application is for individuals to assess skin lesions for potential signs of the most common types of skin cancer.

Device Product Characteristics

Is the device a single product only? Yes
Is this medical device presented as a procedure pack? No
Is the product presented as a system? No
Is the device, or any form of the device, supplied sterile? No
Does the device have a measuring function? No
Is the device, or any form of the device, intended for single use? No
Does the device contain material or ingredients of human origin? No
Does the device contain materials of animal origin? No
Does the device contain materials of recombinant origin? No
Is the device intended to be non-invasive? Yes
Is the device intended to be invasive via a body orifice? No
Is the device intended to be non-invasive and channel or store blood or body liquids for delivery into a patient? No
Is the device intended to be non-invasive and store an organ, part of an organ or body tissue that is to be introduced into a patient? No
Is the device intended to be non-invasive and channel, administer, infuse or store liquid or gas for delivery into a patient? No
Is the device intended to be non-invasive and modify the biological or chemical composition of blood, other body liquids or other liquids intended to be infused into a patient? No
Is the device intended to come in contact with injured skin? No
Is the device intended to be surgically invasive (i.e. will it penetrate the skin)? No
Is the device an active device? Yes
Is the device an active medical device for therapy? No
Is the device an active medical device for diagnosis? No
Is the device used to administer or remove medicine or substances to, or from the body? No
Does the device control, monitor and/or influence an active medical device classified as Class IIb or higher? No
If the device is a single product does it incorporate a medicine? No
If the device is a procedure pack does it contain a separate medicine(s)? No
Is the device intended by the manufacturer to be used for contraception or the prevention of sexually transmitted diseases? No
Is the device intended by the manufacturer to be used for disinfecting, cleaning, rinsing or hydrating contact lens? No
Is the device intended by the manufacturer to be used for disinfecting another medical device other than a device used only to clean by means of physical action? No
Is the device intended by the manufacturer to be non-active and record X-ray diagnostic images? No
Is the device intended by the manufacturer to be used as a blood bag? No

Manufacturer Details	
Manufacturer name:	s 47(1)(b) [redacted]
Manufacturer address:	[redacted]

GMDNS Code and Description

GMDNS code and description:	Medical image management system application software[60724]

Device Category Terms

Device category 1:	Medical Software
Device category 2:	
Device category 3:	

Product Details

Standard Conditions

- The inclusion of the kind of device in the ARTG is subject to compliance with all conditions placed or imposed on the ARTG entry. Refer Part 4-5, Division 2 (Conditions) of the Therapeutic Goods Act 1989 and Part 5, Division 5.2 (Conditions) of the Therapeutic Goods (Medical Devices) Regulations 2002 for relevant information.
- Breaching conditions of the inclusion related to the device of the kind may lead to suspension or cancellation of the ARTG entry; may be a criminal offence; and civil penalties may apply.

Non Standard Conditions

Note: A non standard conditions must not contain semi colons.

To remove, enter item #

Declaration

(a) devices of the kind in question are medical devices; and
(b) devices of that kind are intended for a specified purpose, as ascertained under The definition of a medical device; and
(c) the kind of device is correctly classified according to the medical device classifications; and
(d) devices of that kind comply with the essential principles; and
(e) I:
(i) have available sufficient information to substantiate that compliance with the essential principles; or
(ii) have procedures in place, to ensure that such information can be obtained from the manufacturer within the period specified in the regulations; and
(f) an appropriate conformity assessment procedure has been applied to devices of that kind; and
(g) I:
(i) have available sufficient information to substantiate the application of those conformity assessment procedures; or
(ii) have procedures in place, to ensure that such information can be obtained from the manufacturer within the period specified in the regulations; and
(h) devices of that kind comply with every requirement (if any) relating to advertising applicable under the regulations; and
(i) devices of that kind do not contain substances that are prohibited imports for the purposes of the Customs Act 1901; and
(ia) devices of that kind are not to be used exclusively for one or more of the purposes specified under section 41BEA; and
(j) the information included in or with the application is complete and correct.

I understand the consequences of making a false declaration, as outlined below.

In electronically submitting this application to TGA, I hereby declare that in relation to this medical device the information given in this application and the above statements on this declaration form are current and correct.

PLEASE NOTE:
A false declaration will result in the device entry being removed/cancelled from the ARTG.

Signatory name of the person submitting the application.:

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History

17/08/2016 8:01:00 AM Approved.

Review Completed - Accepted, 17/08/2016)

Record		Date	
Fee	0	Date Paid	17/08/2016
		Date Decision	17/08/2016

Start Dates		Finish Dates		Working Days
Application Received	17/08/2016	Payment Received	17/08/2016	0
Payment Received	17/08/2016	Application Decision	17/08/2016	0
			Total Working Days	0