Medical Device Application

ARTG No : 325343

Class 1
Status : Approved

Application Change history

Application Progress Date	
Date received:	20/10/2019

Review Information	
Review flag:	
Auto review required:	No

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 recombinant origin? No
Does the device contain materials of animal origin? No
Is the device intended to be non-invasive? Yes
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 invasive via a body orifice? 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 as a blood bag? 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 for disinfecting another medical device other than a device used only to clean by means of physical action? No

Application Summary	
Application ID:	DV-2019-DA-17335-1
Sponsor's own reference:	Eyetelligence Pty Ltd
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
Sponsor name:	Eyetelligence Pty Ltd
Sponsor ID:	70834
Agent name:	Compliance Management Solutions
Contact details:	[redacted]
Contact email:	[redacted]

Manufacturer Information	
Manufacturer name:	Eyetelligence Pty Ltd (Australia)[70834]
GMDN code:	Automated retinopathy analysis system application software[58713]
GMDN description:	An individual software application program or group of programs used in combination with one or more retinal imaging devices, such as a fundus camera, for either point-of-care or remote (telemedicine) use. The software provides analysis capabilities for the detection of retinopathy and other retinal diseases for early diagnosis and management in patients at risk, to prevent further deterioration and visual loss. A basic set of programs are included with such systems and can be automatically or manually upgraded to correct programming errors or to add new system capabilities. It may also be used in an off-the-shelf desktop, laptop or tablet computer.
Intended purpose:	The Eyetelligence system is intended to screen and grade Diabetic Retinopathy (DR), Cataract, Aged Related Macular Degeneration (AMD) and Glaucoma in patients/consumers through retinal images. The Eyetelligence system outcomes are intended to be subsequently verified and certified by a qualified medical/eye care professional who will make a clinical decision based on a range of inputs not limited to Eyetelligence outcomes.

Device Category Terms

Attached Documentation

History
23/10/2019 11:02:26 AM Approved. Review Completed - Accepted 23/10/2019)

Record		Date	
Fee:	540	Date Paid:	23/10/2019
		Date Decision:	23/10/2019

Start Dates		Finish Dates		Working Days
Application Received	20/10/2019	Payment Received	23/10/2019	2
Payment Received	23/10/2019	Application Decision	23/10/2019	2
			Total Working Days	4