ARTG No : 296322

Class 1
Status : Approved

Application Change history

Trim: E17-42130 ▮▮▮▮▮▮▮ 7/11/2017)

Application Progress Date

Date received: 14/11/2017

Review Information

Review flag: Returned from applicant review

Auto review required: No

Device Product Characteristics

Is the device, or any form of the device, supplied sterile: No
Is the device intended to be invasive: No
Is the device, or any form of the device, intended for single use: No
Is the device an active device: Yes
Does the device contain material or ingredients of microbial origin: No
Does the device contain material or ingredients of recombinant origin: No
Does the device contain material or ingredients manufactured or formulated using a genetically modified organism: No
Does the device contain material or ingredients of Human Origin: No
Does the device consist of: Single product only
Does the device contain material or ingredients of Animal Origin rendered non-viable: No
Is the device medicated: No
Does the product contain a medicine that is supplied separately in the Australian Market No
Does the product contain a medical device which incorporates a medicine as an integral part and that has an action ancillary to the device: No

Application Summary

Application ID:	DV-2017-DA-17612-1
Submission ID:	DA-2017-06822-1
Sponsor's own reference:	FerriScan AI Export
Application for:	Medical Device - Included (Export Only)
Sponsor name:	Resonance Health Analysis Services Pty Ltd
Sponsor ID:	40814
Agent name:	
Contact details:	▮▮▮▮▮▮
Contact email:	▮▮▮▮▮▮▮▮

Manufacturer Information

Manufacturer name:	Resonance Health Analysis Services Pty Ltd (Australia)[40814]
GMDN code:	MRI system, application program software[40872]
GMDN description:	An individual software program or group of programs, routines or algorithms that add specific image processing and/or analysis capabilities to a magnetic resonance imaging (MRI) system configuration. A basic set of applications programs and routines are included with such computer controlled imaging systems and they can be upgraded to correct programming errors or to add new system capabilities. Some applications software programs or program packages must be combined specific hardware or firmware accessories or configurations in order to function as intended. Applications program packages are typically identified by a proprietary name and "version" or "upgrade" number.
Intended purpose:	For the measurement of R2 and iron concentration in the liver from MRI scans.

Device Category Terms

Device category 1:	Diagnostic and therapeutic radiation devices

Attached Documentation

History

15/11/2017 8:00:43 AM Approved.

Review Completed - Accepted, 15/11/2017)

Record		Date	
Fee:	0	Date Paid:	07/11/2017
		Date Decision:	14/11/2017

Start Dates		Finish Dates		Working Days	
Application Received	14/11/2017	Payment Received	07/11/2017		0