From: s22 [redacted]
To: Devices Clinical
Subject: DA-2015-06850-1 - Clinical request - round 1 [SEC=UNCLASSIFIED]
Date: Tuesday, 6 October 2015 3:34:51 PM
Attachments: DA-2015-06850-1 - Clinical Round 1 - Wirion Embolic Protection System - MD Solutions Pty Ltd.docx

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s22 [redacted]

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Therapeutic Goods Administration
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Australian Government
Department of Health
Therapeutic Goods Administration

Application Audit - Level 2
Clinical Assessment – 1st Round

TRIM Reference: R15/770692

To be completed by DAVS Assessor:

Device UPI	WIRION Embolic Protection System
Sponsor:	MD Solutions Australasia Pty Ltd
Manufacturer:	DA-2015-06850-1
Application ID:	Medtronic Australasia Pty Ltd
Submission ID:	DA-2015-06850-1
DAVS Assessor:	s22
TRIM File No.:	2015/027230 **DATA R15/716655**
Date submitted to TGA:	01/09/2015
Date Referred to Clinical Section:	06/10/2015
Clinical Round:	1

Required Level Of Assessment:	Review of Clinical Evaluation Report suitable for a Level 2 Application Audit (complete Clinical Evidence Checklist in Attachment A)
Manufacturer's Clinical Evaluation Report?	Include TRIM record number where it is located, including preliminary comments and clarification where required.
Notified Body Clinical Evaluation?	If available, provide TRIM record reference number and comments where clarification is required. Eg referenced in Design / Type Examination Report. *Note*: This will not exist for many lower class devices.

To be completed by Clinical Assessor:

Does the submitted clinical data meet the requirements of essential principle 14 of Schedule 1 and Part 8 of Schedule 3 of the *Therapeutic Goods (Medical Devices) Regulations 2002?*	**YES / NO**

Comments & Rationale:

Is additional clinical data required?	**YES / NO**

Specific Questions to be asked: <Subheadings may be required>

Name & Dated Signature of Clinical Assessor:

Name:		**Date:**	
Signature:			

Application Audit Clinical Evidence Checklist

1. Has the manufacturer compiled clinical data for the device in question when used in accordance with the proposed intended purpose?

   ☐ Yes. Go to 2.

   ☐ No. Go to 1a.

   1a. Are there clinical data for a device with which the manufacturer has claimed and demonstrated equivalence? (Consult with MDAS assessor)

      ☐ Yes. Go to 2.

      ☐ No. Go to 1b.

   1b. Has the manufacturer provided an acceptable justification as to why clinical data are not required?

      ☐ Yes. Go to 2.

      ☐ No. The legislative requirements for clinical evidence have not been met.

2. Has the manufacturer submitted an acceptable report detailing the clinical evaluation (critical appraisal) of the clinical data?

   ☐ Yes. Go to 3.

   ☐ No. The legislative requirements for clinical evidence have not been met.

3. Has the clinical evaluation been performed by a person with expertise appropriate to the clinical application of the device?

   ☐ Yes. The legislative requirements for clinical evidence have been met.

   ☐ No. The legislative requirements for clinical evidence have not been met.