March 31, 2021

IMDS Operations B.V.
Edwin Schulting
CEO
Ceintuurbaan Noord 150
Roden, Drenthe 9301 NZ
Netherlands

Re: K210110
Trade/Device Name: Guidion Catheter
Regulation Number: 21 CFR 870.1250
Regulation Name: Percutaneous Catheter
Regulatory Class: Class II
Product Code: DQY
Dated: January 14, 2021
Received: January 19, 2021

Dear Edwin Schulting:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part

801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Lydia Glaw
Assistant Director
DHT2C: Division of Coronary
and Peripheral Interventional Devices
OHT2: Office of Cardiovascular Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K210110

Device Name
Guidion Catheter

Indications for Use *(Describe)*
Guidion catheters are intended to be used in conjunction with guide catheters to access discrete regions of the coronary and/or peripheral vasculature, and to facilitate placement and exchange of guide wires and other interventional devices.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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510(k) Summary

Date Prepared: March 22nd , 2021

Submitter's Name / Contact Person

Manufacturer
IMDS Operations BV
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9301 NZ Roden , The Netherlands
Establishment Registration #3007740583

Contact Person
Florence Wagter
Director of Quality and Regulatory
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General Information

Trade Name	Guidion Catheter
Common/ Usual Name	Rapid Exchange Guide Extension Catheter
Classification Name	Catheter, percutaneous
Product Code	DQY
Predicate Device	K172090, Guideliner V3 Catheter, Vascular Solutions, Inc.
Reference Device	None

Device Description

The Guidion catheter is a single lumen rapid exchange catheter offered in sizes being compatible with 5F; 6F; 7F and 8F guide catheters and may be placed over an guide wire. The 150cm long device has a stainless steel shaft section. The stainless steel shaft is followed distally by a 25cm lumen section.

The Guidion catheter has a radiopaque distal end which enables visibility while using standard fluoroscopic methods. The device has two positioning marks located at 95cm and 105cm from the distal tip, respectively.

The Guidion catheter is delivered through a guiding catheter resulting in an inner diameter that is approximately 1 French smaller than the guide catheter.
The Guidion catheter has a proximal hub which indicates guide catheter compatibility.

Intended Use

Guidion catheters are intended to be used in conjunction with guide catheters to access discrete regions of the coronary and/or peripheral vasculature, and to facilitate placement and exchange of guide wires and other interventional devices.

Technological Characteristics Comparison

The Guidion is similar in design to the predicate device and both are Rapid Exchange Guide Extension Catheters intended to be used to access discrete regions of the coronary and/or peripheral vasculature, and to facilitate placement and exchange of guide wires and other interventional devices.

#	Item	Guidion catheter	Guideliner V3 Catheter
	Model number (s)	G50F25150, G60F25150, G70F25150 & G80F25150	5569, 5571, 5572 & 5573
1	Type clinically based	Guide Extension catheter	Guide Extension catheter
2	Design construction	Rx, single lumen	Rx, single lumen
2	Distal shaft material	Stainless steel coiling embedded in a polymer shaft	Stainless steel coiling embedded in a polymer shaft
3	Proximal shaft	Stainless steel	Stainless steel
4	Distal radiopague markers	1	1
5	Radiopaque tip/ marker material	TPE/ Tungsten	Platinum/ Iridium
6	Effective length	150 (cm)	150 (cm)
7	Length distal shaft	25 (cm)	25 (cm)
8	Required guide catheter ID	5F 1.42 (mm) 6F 1.78 (mm) 7F 1.98 (mm) 8F 2.24 (mm	5F 1.42 (mm) 6F 1.78 (mm) 7F 1.98 (mm) 8F 2.24 (mm)
9	Tip design shape	Straight	Straight
10	Inner diameter distal shaft	5F 1.04 (mm) 6F 1.42 (mm) 7F 1.57 (mm) 8F 1.80 (mm)	5F 1.17 (mm) 6F 1.42 (mm) 7F 1.57 (mm) 8F 1.80 (mm)
11	Product coating	Hydrophilic	Silicon

With the exception of
dimensional, material and package configuration differences, the Guidion is similar in design and technological characteristics to the predicate device. The dimensional, material and package configuration differences were successfully evaluated in performance tests.

Substantial Equivalence and Summary of Studies

The technological differences between the subject and predicate devices have been evaluated through performance and biocompatibility tests and results did not raise new questions of safety or effectiveness. The Guidion Rapid Exchange Guide Extension catheter is substantially equivalent to the specified predicate device based on comparisons of the device functionality, technological characteristics, and indications for use.

The device design has been verified through the following tests:

1) Kind resistance/ flexibility
2) Radiopacity
3) Catheter bond strength
4) Crossing profile
5) Catheter preparation, deployment & retraction
6) Hub bond strength
7) Proximal shaft depth marker position
8) Torque strength
9) Effective length
10) Length distal shaft
11) Inner diameter
12) Coating Particulate Evaluation
13) Coating integrity
14) Packaging integrity

Device samples passed the following biocompatibility tests performed in accordance with ISO 10993-1:

- Cytotoxicity
- Sensitization
- Irritation
- Systemic toxicity
- Pyrogenicity
- Hemocompatibility

The results of the verification tests met the specified acceptance criteria and did not raise new safety or performance issues. Therefore, the Guidion Rapid Exchange Guide Extension catheter is substantially equivalent to the predicate device.