April 17, 2025

IMDS Operations B.V.
Edwin Schulting
CEO
Ceintuurbaan Noord 150
Roden, NL9301NZ
Netherlands

Re: K242337
Trade/Device Name: FlowGuide (FG60F); GuidionShort (GS60F)
Regulation Number: 21 CFR 870.1250
Regulation Name: Percutaneous Catheter
Regulatory Class: Class II
Product Code: DQY
Dated: March 17, 2025
Received: March 17, 2025

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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,

Brian D. Pullin -S

for Lydia Glaw
Assistant Director
DHT2C: Division of Coronary and
Peripheral Intervention 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: 07/31/2026
See PRA Statement below.

510(k) Number *(if known)*
K242337

Device Name
FlowGuide (FG60F), GuidionShort (GS60F)

Indications for Use *(Describe)*
The Guide extension family 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. The Guide extension family catheters are contraindicated in vessels less than 2.5mm in diameter, vessels in the neurovasculature, and the venous system.

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

[As required by 21 CFR 807.92]

Date Prepared: August 5th, 2024

Submitter's Name / Contact Person

Manufacturer
IMDS Operations BV
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Establishment Registration #3007740583

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Aljosja Kot
Director of Quality and Regulatory
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General Information

Trade Name	FlowGuide and GuidionShort
Common/ Usual Name	Rapid Exchange Guide Extension Catheter
Classification Name	Catheter, percutaneous
Product Code	DQY
Predicate Device	K210110, Guidion Rapid Exchange Guide Extension Catheter, IMDS Operations B.V.
Reference Device	K212211, TrapLiner, Vascular Solutions, LLC

Device Description

The FlowGuide and GuidionShort are single lumen rapid exchange catheters being compatible with 6F and larger guide catheters and may be placed over either an exchange length or 180cm guide wire. The 150cm long device has a stainless-steel shaft section. The stainless-steel shaft is followed distally by a 15 cm lumen section.

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

The FlowGuide has 9 perfusion holes in the distal shaft intended to reduce pressure dampening.

Intended Use

FlowGuide and GuidionShort 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. The Guide extension family catheters are contraindicated in vessels less than 2.5mm in diameter, vessels in the neurovasculature, and the venous system.

Technological Characteristics Comparison

The FlowGuide and GuidionShort are 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	FlowGuide and GuidionShort catheter	Guidion Catheter
	Model number (s)	FG60F, GS60F	G60F25150
1	Type clinically based	Guide Extension catheter	Guide Extension catheter
2	Design construction	Rx, single lumen	Rx, single lumen
3	Distal shaft material	Stainless steel coiling embedded in a polymer shaft	Stainless steel coiling embedded in a polymer shaft
4	Proximal shaft	Stainless steel	Stainless steel
5	Distal radiopaque markers	1	1
6	Proximal radiopaque marker distal shaft	1	0
7	Radiopaque marker material	TPE/ Tungsten	TPE/ Tungsten
8	Effective length	150 (cm)	150 (cm)
9	Length distal shaft	15 (cm)	25 (cm)
10	Required guide catheter ID	6F 1.78 (mm)	6F 1.78 (mm)
11	Tip design shape	Straight	Straight
12	Inner diameter distal shaft	6F 1.42 (mm)	6F 1.42 (mm)
13	Distal shaft perfusion holes	Yes, FG60F only	No
14	Product coating	Hydrophilic	Hydrophilic

With the exception of a shorter distal shaft length and perfusion holes for the FlowGuide the products are similar in design and technological characteristics to the predicate device. The shorter distal shaft length and perfusion holes are known features as evaluated from the reference device and 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 FlowGuide and GuidionShort Guide Extension catheters are 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) Visual inspection
2) Kink resistance/ flexibility
3) Radiopacity
4) Catheter bond strength
5) Crossing profile
6) Catheter preparation, deployment & retraction
7) End stop strength
8) Tip length
9) Coating lubricity
10) Perfusion flow
11) Corrosion resistance
12) Torque strength
13) Effective length
14) Length distal shaft
15) Inner diameter
16) Coating Particulate Evaluation
17) Coating integrity
18) Packaging integrity

FlowGuide and GuidionShort are meeting the requirements for biocompatibility 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 FlowGuide and GuidionShort Rapid Exchange Guide Extension catheters are substantially equivalent to the predicate device.