September 3, 2024

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

Re: K241611
Trade/Device Name: ShapeIT
Regulation Number: 21 CFR 870.1250
Regulation Name: Percutaneous Catheter
Regulatory Class: Class II
Product Code: DQY
Dated: June 5, 2024
Received: June 5, 2024

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.

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,

Lydia S. Glaw -S

Digitally signed by Lydia S. Glaw -S
Date: 2024.09.03 14:40:08 -04'00'

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)*
K241611

Device Name
ShapeIT

Indications for Use *(Describe)*
The ShapeIT catheter with hydrophilic coating is intended to support a guide wire during access of coronary and/or peripheral vasculature.
The device is contraindicated for use in the neurovasculature.

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: May 30, 2024

Submitter's Name / Contact Person

Manufacturer
IMDS Operations BV
Ceintuurbaan Noord 150

9301 NZ Roden, The Netherlands
Establishment Registration #3007740583

Contact Person
Aljosja Kot
Director Quality Assurance and Regulatory Affairs
Tel: 0031651453880
Fax: 0031508200231

General Information

Trade Name	ShapeIT
Common/ Usual Name	Catheter
Classification Name	Catheter, percutaneous
Predicate Device	K223728, Micro Rx Catheter, IMDS Operations B.V.
Reference Device	K182570, Venture 0.014 Catheter, Vascular Solutions, LLC
Reference Device	K210647, SuperCross 120˚angled tip, Vascular Solutions, LLC

Device Description

The ShapeIT is a guide wire support catheter intended to be used in the coronary and/ or peripheral vasculature for patients suffering from coronary or peripheral artery disease. The target lesion can be reached by using the femoral or brachial approach. The ShapeIT is a single lumen 0.014" rapid exchange catheter. The 135 cm long device has a stainless-steel shaft section. The stainless-steel shaft is followed distally by a 15 cm lumen section. The ShapeIT distal end is preshaped to support guidewire redirection in bifurcations.

The ShapeIT catheter has a radiopaque distal tip which enables visibility while using standard fluoroscopic methods. The device has two positioning marks located at 95cm and 105cm from the distal tip, respectively. Furthermore, two distal shaft exit markers are located at 110 cm and 120 cm to indicate the distal shaft exit.

Intended Use

The ShapeIT catheter with hydrophilic coating is intended to support a guide wire during access of coronary and/or peripheral vasculature.
The device is contraindicated for use in the neurovasculature.

Technological Characteristics Comparison

The ShapeIT is similar in design to the predicate device and both are rapid exchange single lumen, percutaneous catheters intended to access discrete regions of the coronary and peripheral vasculature and facilitate placement of guidewires.

#	Item	ShapeIT Guidewire support catheter	Micro Rx Guidewire support catheter	Equivalent*
	Model number	SI014135	RX135	
1	Type clinically based	Rapid exchange single lumen guidewire support catheter	Rapid exchange single lumen guidewire support catheter	Y
2	Distal shaft material	Pebax / Polyethylene	Pebax / Polyethylene	Y
3	Distal shaft reinforcement	Stainless steel	Stainless steel	Y
4	Proximal shaft	Stainless steel	Stainless steel	Y
5	Rapid Exchange guidewire lumens	1	1	Y
6	Number of guidewire distal exit ports	1	1	Y
7	Radiopaque marker material	TPE / Tungsten	TPE / Tungsten	Y
8	Effective Length or Usable Length	135 cm	135 cm	Y
9	Exit Marker location (from tip)	95 and 105 cm	95 and 105 cm	Y
10	Guidewire compatibility	0.014 inch	0.014 inch	Y
11	Distal shaft outer diameter	1.1 mm	1.1 mm	Y
12	Minimum Guiding Catheter size	5 Fr	5 Fr	Y
13	Tip design / shape	Angulated	Straight	D
14	Shapeable distal section	Yes	No	D
15	Hydrophilic coating distal shaft	present	present	Y
16	Hydrophilic coating material	PUR / PVP hydrophilic coating	PUR / PVP hydrophilic coating	Y
17	Inner lumen coating	MDX	MDX	Y

With the exception of the angulated tip and shapeable distal section, the ShapeIT is similar in design and technological characteristics to the predicate device. An angulated tip and shapeable distal section are known feature as evaluated from the references device and was 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 ShapeIT guide wire support 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) Kink resistance/ flexibility
2) Device introduction, deployment and retraction
3) Radiopacity
4) Distal tip length
5) Tensile strength
6) Effective length
7) Shaft inner diameter
8) Corrosion resistance
9) Visual inspection
10) Torque robustness
11) Shape retention
12) Redirecting a guidewire in a bifurcation
13) Outer diameter
14) Surface coating lubricity
15) Coating integrity
16) Coating particulate evaluation
17) Packaging integrity

ShapeIT is 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 ShapeIT guide wire support catheter is substantially equivalent to the predicate device.