July 13, 2023

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

Re: K223728
Trade/Device Name: Micro Rx
Regulation Number: 21 CFR 870.1250
Regulation Name: Percutaneous Catheter
Regulatory Class: Class II
Product Code: DQY
Dated: June 12, 2023
Received: June 12, 2023

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,

Samuel G. Raben -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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K223728

Device Name
Micro Rx

Indications for Use *(Describe)*
The Micro Rx 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: November 10th, 2022

Submitter's Name / Contact Person

Manufacturer
IMDS Operations BV
Ceintuurbaan Noord 150

9301 NZ Roden, The Netherlands
Establishment Registration #3007740583

Contact Person
Florence Wagter
Principle Associate Quality Assurance/ Regulatory Affairs
Tel: 0031651453880
Fax: 0031508200231

General Information

Trade Name	Micro Rx
Common/ Usual Name	Catheter
Classification Name	Catheter, percutaneous
Predicate Device	K182570, Venture 0.014" Catheter, Vascular Solutions, LLC
Reference Device	K200324 NHancer Rx, IMDS Operations B.V.

Device Description

The Micro Rx 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 Micro Rx 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 Micro Rx 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 Micro Rx 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 Micro Rx 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	Micro Rx Guidewire support catheter	Venture 0.014" catheter
	Model number	RX135	5820
1	Type clinically based	Rapid exchange single lumen guidewire support catheter	Rapid exchange single lumen guidewire support catheter
2	Distal shaft material	Polymeric	Polymeric
3	Distal shaft reinforcement	Stainless steel	Stainless steel

4	Proximal shaft	Stainless steel	Stainless steel
5	Rapid Exchange guidewire lumens	1	1
6	Number of guidewire distal exit ports	1	1
7	Radiopaque marker	Present	Present
8	Effective Length or Usable Length	135 cm	145 cm
9	Exit Marker location (from tip)	95 and 105 cm	95 and 105 cm
10	Guidewire compatibility	0.014 inch	0.014 inch
11	Shaft outer diameter	1.0 mm	1.37 mm
12	Minimum Guiding Catheter size	5 Fr	6 Fr
13	Tip design / shape	Straight	Straight
14	Hydrophilic coating distal shaft	present	present
15	Hydrophilic coating material	Hydrophilic	Hydrophilic
16	Inner lumen coating	MDX	Not known

With the exception of dimensional configuration differences, the Micro Rx 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 Micro Rx 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) Torque robustness
9) Outer diameter
10) Surface coating lubricity
11) Coating integrity
12) Coating particulate evaluation
13) Packaging integrity

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