July 15, 2021

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

Re: K210431
Trade/Device Name: ReCross
Regulation Number: 21 CFR 870.1250
Regulation Name: Percutaneous Catheter
Regulatory Class: Class II
Product Code: DQY
Dated: February 9, 2021
Received: February 12, 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,

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)*
K210431

Device Name
ReCross

Indications for Use *(Describe)*
The ReCross Dual Lumen guide wire support catheter with hydrophilic coating is intended to support a guide wire during access of coronary and/or peripheral vasculature and allows for exchange of guide wires and provides a conduit for the delivery of diagnostic contrast agents. The catheter is not intended 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.

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510(k) Summary

[As required by 21 CFR 807.92]

Date Prepared: February 8th , 2021

Submitter's Name / Contact Person

Manufacturer
IMDS Operations BV
Ceintuurbaan Noord 150
9301 NZ Roden, The Netherlands
Establishment Registration #3007740583

Contact Person
Florence Wagter
Director of Quality and Regulatory
Tel: 0031651453880
Fax: 0031508200231

General Information

Trade Name	ReCross
Common/ Usual Name	Dual lumen catheter
Classification Name	Catheter, percutaneous
Predicate Device	K200324, NHancer Rx, dual lumen catheter, IMDS Operations B.V.
Reference Device	None

Device Description

The ReCross is a dual lumen catheter intended to use in the coronary and/or peripheral vasculature. The ReCross is a 0.014" Over The Wire (OTW) guide wire support catheter. The ReCross has two over the wire OTW lumens that runs the length of the catheter. The ReCross has two depth markings located at 95 cm and 105 cm from the distal tip. The ReCross has a radiopaque marker identifying the distal end of the catheter, a second radiopaque marker in the stylet lumen located 8 mm from the distal tip identifies the distal end of the OTW lumen and a third radiopaque marker in the tip lumen located at 12 mm from the distal tip indentifying the side port.
To reduce friction in the guide catheter and vasculature, the distal shaft is fitted with a hydrophilic coating. To reduce friction of the guide wire in the lumen, the entire lumens of the ReCross are coated with MDX (silicone) coating.
To ease catheter loading into the hemostasis device and the guiding catheter a removable stylet is placed in the stylet lumen

Intended Use

The ReCross Dual Lumen guide wire support catheter with hydrophilic coating is intended to support a guide wire during access of coronary and/or peripheral vasculature and allows for exchange of guide wires and provides a conduit for the delivery of diagnostic contrast agents. The catheter is not intended for use in the neurovasculature.

Technological Characteristics Comparison

The ReCross is similar in design to the predicate device and both are dual lumen, percutaneous catheters intended to access discrete regions of the coronary and peripheral vasculature, facilitate placement and exchange of guidewires and sub selectively infuse agents.

#	Item	ReCross OTW dual lumen guidewire support catheter	NHancer Rx dual lumen guidewire support catheter
	Model number	RC1414025	NRX1413518
1	Type clinically based	Dual lumen guidewire support catheter	Dual lumen guidewire support catheter
2	Shaft material	Polymeric	Polymeric

3	Shaft reinforcement	Stainless steel stiffening wire & braiding	Stainless steel stiffening wire & braiding
4	OTW Guidewire lumens	2	1
5	Rapid Exchange guidewire lumens	0	1
6	Number of guidewire distal exit ports	3	2
7	Strain Relief	present	present
8	Hub and Luer Lock	Female, 6% taper and screw conform NEN EN ISO 80369-7	Female, 6% taper and screw conform NEN EN ISO 80369-7
9	Radiopaque marker material	Tungsten	Tungsten
10	Effective Length or Usable Length	140 cm	135 cm
11	Exit Marker location (from tip)	95 and 105 cm	95 and 105 cm
12	Guidewire compatibility	0.014 inch	0.014 inch
13	Maximum injection pressure	150 psi	300 psi
14	Shaft cross sectional area	0.58 mm^2	0.58 mm^2
15	Minimum Guiding Catheter size	5 Fr	5 Fr
16	Tip design / shape	Straight	Straight
17	Tip material	Polymeric	Polymeric
18	Hydrophilic coating distal shaft	present	present
19	Hydrophilic coating material	Hydrophilic coating	Hydrophilic coating
20	Inner lumen coating	Yes	Yes

With the exception of dimensional configuration differences, the ReCross 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 ReCross dual lumen 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) Guide wire insertion
3) Radiopacity
4) Distal tip length
5) Tensile strength
6) Catheter body burst
7) Contrast medium flow rate
8) Leak testing
9) Effective length
10) Shaft inner diameter
11) Outer diameter
12) Surface coating lubricity
13) Coating Integrity
14) Coating Particulate Evaluation
15) Packaging integrity

ReCross 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 ReCross dual lumen catheter is substantially equivalent to the predicate device.