August 6, 2020

IMDS Operations B.V.
Edwin Schulting
CEO
Ceintuurbaan Noord 150
Roden, 9301 NA Nl

Re: K200324
Trade/Device Name: NHancer Rx
Regulation Number: 21 CFR 870.1250
Regulation Name: Percutaneous Catheter
Regulatory Class: Class II
Product Code: DQY
Dated: July 2, 2020
Received: July 6, 2020

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,

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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K200324

Device Name
NHancer Rx

Indications for Use *(Describe)*
The NHancer Rx Dual Lumen Rapid Exchange 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: August 6th, 2020

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
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General Information

Trade Name	NHancer Rx
Common/ Usual Name	Dual lumen catheter
Classification Name	Catheter, percutaneous
Predicate Device	K162467, Twin-Pass torque, dual access catheter, Vascular solutions, Inc.
Reference Device	K121077, NHancer guidewire support catheter

Device Description

The NHancer™Rx is a dual lumen catheter intended to use in the coronary and/or peripheral vasculature. The NHancer™Rx is a 0.014" Rapid Exchange (Rx) guide wire support catheter. The NHancer™Rx has an over the wire (OTW) lumen that runs the length of the catheter and a rapid exchange (RX) delivery lumen on the distal end. The NHancer™Rx has an effective length of 135 cm and is compatible with 0.014"/0.36mm or smaller guide wires. The NHancer™Rx has two depth markings located at 95 cm and 105 cm from the distal tip. The NHancer™Rx has a radiopaque marker identifying the distal end of the catheter and a second radiopaque marker located 8 mm from the distal tip identifies the distal end of the OTW lumen.
To reduce friction in the guide catheter and vasculature, the distal 15 cm of the shaft is fitted with a hydrophilic coating. To reduce friction of the guide wire in the lumen, the entire lumens of the NHancer Rx are coated with MDX (silicone) coating.
To ease catheter loading into the hemostasis device and the guiding catheter a removable stylet (9) is placed in the OTW lumen

Intended Use

The NHancer Rx Dual Lumen Rapid Exchange 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 NHancer Rx 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	NHancer Rx dual lumen guidewire support catheter	Twin-Pass Torque dual access catheter
	Model number	NRX1413518	5201
1	Type clinically based	Dual lumen guidewire support catheter	Dual lumen guidewire support catheter
2	Shaft material	Polymeric	Polymeric

3	Shaft reinforcement	Stainless steel	Stainless steel
4	OTW Guidewire lumens	1	1
5	Rapid Exchange guidewire lumens	1	1
6	Number of guidewire distal exit ports	2	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	Pt/Ir
10	Effective Length or Usable Length	135 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	300 psi	300 psi
14	Minimum Guiding Catheter size	5 Fr	5 Fr
15	Tip design / shape	Straight	Straight
16	Tip material	Polymeric	Polymeric
17	Hydrophilic coating distal shaft	present	present
18	Hydrophilic coating material	PUR / PVP hydrophilic coating	Not known
19	Inner lumen coating	Hydrophobic	Not known
20	Removable stylet in OTW lumen	Yes	No
21	Distal shaft design	Oval	Round

With the exception of dimensional, material and package configuration differences, the NHancer 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 NHancer Rx 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

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 NHancer Rx dual lumen catheter is substantially equivalent to the predicate device.