January 21, 2020

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

Re: K191229
Trade/Device Name: TrapIt
Regulation Number: 21 CFR 870.1250
Regulation Name: Percutaneous Catheter
Regulatory Class: Class II
Product Code: DQY
Dated: December 16, 2019
Received: December 18, 2019

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,

Lydia Glaw
Assistant Director
DHT2C: Division of Coronary
and Peripheral Interventional 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)*
K191229

Device Name
TrapIt

Indications for Use *(Describe)*
The TrapIT Trapping Balloon Catheter is indicated to facilitate interventional device exchange while maintaining wire position in patients undergoing PCI procedures. TrapIT Trapping Balloon Catheter is not intended for use outside of the guide catheter.

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: April 26th, 2019

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 Assurance and Regulatory Affairs
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General Information

Trade Name	TrapIt
Common/ Usual Name	Trapping Balloon Catheter
Classification Name	Catheter, percutaneous
Product Code	DQY
Predicate Device	K162253, Trapper Exchange Device, Creganna Medical

Device Description

The TrapIt Trapping Balloon Catheters have an integrated shaft system and a balloon near the distal tip. The shaft has a lumen which is used for inflation of the balloon with contrast medium. As aid in positioning the balloon in a guide catheter a tactile feedback stop is integrated in the shaft. The shaft of the 100 cm compatible TrapIt has a shaft depth marking that aid in gauging balloon catheter position relative to the guiding catheter tip when used in 90 cm guide catheters.

Intended Use

The TrapIt Trapping Balloon Catheter is indicated to facilitate interventional device exchange while maintaining wire position in patients undergoing PCI procedures. TrapIt Trapping Balloon Catheter is not intended for use outside of the guide catheter.

Technological Characteristics Comparison

The TrapIt is similar in design to the predicate device and both are dedicated trapping, percutaneous balloon catheters intended to facilitate interventional device exchange in a PCI procedure. With the exception of dimensional, material and package configuration differences, the TrapIt 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 TrapIt Trapping Balloon 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) Radiopacity
3) Catheter bond strength
4) Tip bond strength
5) Crossing profile
6) Balloon preparation, deployment & retraction
7) Balloon rated burst
8) Balloon fatigue
9) Balloon compliance
10) Effective length
11) Tip length
12) Balloon inflation time
13) Balloon deflation time
14) Shaft outer diameter
15) Coating Particulate Evaluation
16) 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 TrapIt Trapping Balloon Catheter is substantially equivalent to the predicate device.