August 14, 2026

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

Re: K260559
Trade/Device Name: NHanceIT (NX31413525)
Regulation Number: 21 CFR 870.1250
Regulation Name: Percutaneous Catheter
Regulatory Class: Class II
Product Code: DQY
Dated: July 15, 2026
Received: July 15, 2026

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 Management System Regulation (QMSR) (21 CFR Part 820), which includes, but is not limited to, ISO 13485 clause 7.3 (Design controls), ISO 13485 clause 8.3 (Nonconforming product), ISO 13485 clause 8.5.2 (Corrective action), and ISO 13485 clause 8.5.3 (Preventative action). Please note that regardless of whether a change requires premarket review, the QMSR requires device manufacturers to review and approve changes to device design and production (ISO 13485 clause 7.3 and ISO 13485 clause 7.5) and document changes and approvals in the Medical Device File (ISO 13485 clause 4.2.3).

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 Management System Regulation (QMSR) (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.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

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,

JENNY R. KATSNELSON -S

Digitally signed by JENNY R. KATSNELSON -S
Date: 2026.08.14 16:50:51 -04'00'

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: 07/31/2026
See PRA Statement below.

510(k) Number *(if known)*
K260559

Device Name
NHanceIT

Indications for Use *(Describe)*
The IMDS NHanceIT Guide Wire Support Catheter with hydrophilic coating is a guidewire exchange and infusion device designed for use in the coronary and/or peripheral vasculature. The catheter is intended to support a guidewire during access of coronary and/or peripheral vasculature and allows for exchange of guidewires and provide 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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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510(k) Summary – K262396

[As required by 21 CFR 807.92]

Date Prepared: December 15, 2025

Submitter's Name / Contact Person

Manufacturer
IMDS Operations BV
Ceintuurbaan Noord 150

9301 NZ Roden, The Netherlands
Establishment Registration #3007740583

Contact Person
Aljosja Kot
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General Information

Trade Name	NHanceIT
Common/ Usual Name	Catheter
Classification Name	Catheter, percutaneous
Predicate Device	K191560, Turnpike LP Catheter, Teleflex Medical LLC
Reference Device	K200324, NHancer Rx guide wire support catheter, IMDS Operations B.V.

Device Description

The NHanceIT is a guide wire support catheter intended to be used in the coronary and/ or peripheral vasculature. The NHanceIT is a 0.014" OTW guide wire support catheter. The target lesion can be reached by using the femoral or brachial approach. The catheter has a distal port, which accesses the guide wire lumen. The guide wire lumen begins at the proximal end and terminates at the distal tip. The catheter has a radiopaque tip section to indicate the distal end of the support catheter. The tip is visible under X-ray. The length of the catheter is designed that the distal end of the catheter may be used to navigate to lesions in more distal vessels. The distal part carries a deformable atraumatic tip to help center the wire in the vessel.

Intended Use/Indications for Use

The IMDS NHanceIT Guide Wire Support Catheter with hydrophilic coating is a guidewire exchange and infusion device designed for use in the coronary and/or peripheral vasculature. The catheter is intended to support a guidewire during access of coronary and/or peripheral vasculature and allows for exchange of guidewires and provide a conduit for the delivery of diagnostic contrast agents.
The device is contraindicated for use in the neurovasculature.

Technological Characteristics Comparison

The NHanceIT is similar in design to the predicate device and both are OTW single lumen guide wire support catheters intended to support a guide wire during access of coronary and/ or peripheral vasculature, allow for exchange of guide wires and provide a conduit for the delivery of diagnostic contrast agents.

#	Item	NHanceIT	Turnpike LP	Equivalent* (Yes or Different)
	Model number	NX31413525	5638	
1	Type clinically based	Over the wire single lumen guide wire support catheter	Over the wire single lumen guide wire support catheter	Y

2	Shaft material	Pebax / Polyethylene	Unknown	D
3	Shaft reinforcement	Stainless steel	Stainless steel	Y
4	Number of guide wire distal exit ports	1	1	Y
5	Over the wire guide wire lumens	1	1	Y
6	Radiopaque marker material	TPE / Tungsten	Unknown	D
7	Effective Length or Usable Length	135 cm	135 cm	Y
8	Exit Marker location (from tip)	95 and 105 cm	No markers	D
9	Guide wire compatibility	0.014 inch	0.014 inch	Y
10	Distal tip outer diameter	0.58 mm	0.57 mm	D
11	Distal shaft outer diameter	0.73 mm	0.73 mm	Y
12	Proximal shaft outer diameter	1.07 mm	0.96 mm	D
13	Minimum Guiding Catheter size	5 Fr	5 Fr	Y
14	Tip design / shape	Straight	Straight	Y
15	Hydrophilic coating distal shaft	Present	Present	Y
16	Hydrophilic coating material	PUR / PVP hydrophilic coating	Unknown	D
17	Inner lumen coating	MDX	Unknown	D

The NHanceIT is similar in design and technological characteristics to the predicate device. The differences in dimensions and materials were successfully evaluated in performance tests against the predicate device.

The reference device has a material shaft design equal to the NHanceIT and is manufactured in the same cleanrooms and with similar production equipment. The material composition does not raise different questions regarding effectiveness and/or safety compared to the predicate.

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 supported substantial equivalence.

The NHanceIT 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) Leak testing
11) Catheter burst
12) Infusion flow rate
13) Surface coating lubricity
14) Coating integrity
15) Coating particulate evaluation
16) Catheter bond strength and tip pull
17) Packaging integrity

The NHanceIT is meeting the requirements for biocompatibility in accordance with ISO 10993-1:

- Cytotoxicity
- Sensitization
- Irritation
- Systemic toxicity
- Hemocompatibility
- Pyrogenicity

The results of the verification tests met the specified acceptance criteria and supported substantial equivalence.

Therefore, the NHanceIT guide wire support catheter is substantially equivalent to the predicate device.