April 22, 2025

Goodman Co., Ltd.
% Nozomi Yagi
Senior Regulatory Affairs Manager
Infraredx
28 Crosby Drive
Suite 100
Bedford, Massachusetts 01730

Re: K243944
Trade/Device Name: Aperta NSE PTA Balloon Dilatation Catheter
Regulation Number: 21 CFR 870.1250
Regulation Name: Percutaneous Catheter
Regulatory Class: Class II
Product Code: PNO
Dated: December 20, 2024
Received: April 7, 2025

Dear Nozomi Yagi:

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 System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 systems (QS) regulation (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,

ARIEL G. ASH-SHAKOOR -S

Digitally signed by ARIEL G. ASH-SHAKOOR -S
Date: 2025.04.22 09:27:51 -04'00'

For

Gregory O'Connell
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)*
K243944

Device Name
Aperta NSE PTA Balloon Dilatation Catheter

Indications for Use *(Describe)*
The Aperta NSE PTA Balloon Dilatation Catheter is indicated for percutaneous transluminal angioplasty (PTA) of lesions in peripheral arteries, including iliac, femoral, ilio-femoral, popliteal and infra-popliteal arteries, and for the treatment of obstructive lesions of native or synthetic arteriovenous dialysis fistulae. This device is also indicated for treatment of in-stent restenosis of balloon expandable and self-expanding stents in the peripheral vasculature. This device is not for use in the coronary or neuro-vasculature including carotid arteries.

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.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

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510(k) #: K243944

510(k) Summary

Prepared on: 2025-04-22

Contact Details

21 CFR 807.92(a)(1)

Applicant Name:	Goodman Co., Ltd.
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Applicant Contact:	Kanechika Aida
Applicant Contact Email:	Kanechika.Aida@goodmankk.com
Correspondent Name:	Infraredx, Inc.
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Correspondent Contact Telephone:	(781) 221-0053
Primary Correspondent Contact:	Nozomi Yagi
Primary Correspondent Contact Email:	nyagi@infraredx.com
Secondary Correspondent Contact:	Stephen Sum, Ph.D.
Secondary Correspondent Contact Email:	ssum@infraredx.com

Device Name

21 CFR 807.92(a)(2)

Device Trade Name:	Aperta NSE™ PTA Balloon Dilatation Catheter
Common Name:	Percutaneous catheter
Classification Name:	Catheter, Percutaneous, Cutting/Scoring
Regulation Number:	870.1250
Product Codes:	PNO

Legally Marketed Predicate Device

21 CFR 807.92(a)(3)

Predicate #	Predicate Trade Name	Product Code
K232013	Aperta NSE™ PTA Balloon Dilatation Catheter	PNO

Device Description Summary

21 CFR 807.92(a)(4)

The Aperta NSE™ PTA Balloon Dilatation Catheter (Aperta NSE PTA) is an over-the-wire (OTW) type catheter used for percutaneous transluminal angioplasty of lesions in peripheral arteries and obstructive lesions of arteriovenous dialysis fistula. The Aperta NSE PTA catheter is designed with protruding polymer elements parallel to the balloon to aid dilatation of stenotic lesions that are difficult to expand with a conventional balloon.

Intended Use/Indications for Use

21 CFR 807.92(a)(5)

The Aperta NSE PTA Balloon Dilatation Catheter is indicated for percutaneous transluminal angioplasty (PTA) of lesions in peripheral arteries, including iliac, femoral, ilio-femoral, popliteal and infra-popliteal arteries, and for the treatment of obstructive lesions of native or synthetic arteriovenous dialysis fistulae. This device is also indicated for treatment of in-stent restenosis of balloon expandable and self-expanding stents in the peripheral vasculature. This device is not for use in the coronary or neuro-vasculature including carotid arteries.

Indications for Use Comparison 21 CFR 807.92(a)(5)

The subject device shares identical indications for use language with the predicate device.

Technological Comparison 21 CFR 807.92(a)(6)

Compared to the predicate device, the subject device contains the following key modifications:

- **Balloon length**: The subject device includes balloon lengths of 100 and 150 mm, compared to the predicate device's 40 mm length, and
- **Radiopaque (RO) markers**: The longer balloon models of the subject device has two (2) RO markers at the distal end of the balloon and one (1) at the proximal end, reversing the configuration of the predicate device, which has one (1) at the distal end and two (2) at the proximal end.

The subject device has equivalent technological characteristics (i.e., design, material, chemical composition, principle of operation) as the predicate device. While there are technological differences, the non-clinical testing results have demonstrated that the technological differences do not raise new questions of safety and effectiveness.

Non-Clinical and/or Clinical Tests Summary & Conclusions 21 CFR 807.92(b)

The following non-clinical testing was performed in accordance with the FDA Guidance Document titled *Peripheral Percutaneous Transluminal Angioplasty (PTA) and Specialty Catheters* issued on April 14, 2023 to demonstrate that the subject device is substantially equivalent to the predicate device:

Bench testing

- Visual verification
- Dimensional verification (crossing profile and other)
- Balloon compliance & RBP
- Balloon RBP in stent
- Catheter body burst pressure
- Dimensional verification (element height)
- Coating integrity (Pre & Post)
- Simulated use
- Balloon inflation/deflation time
- Balloon fatigue
- Torque strength
- Flexibility and kink
- Dimensional verification (Balloon element working length)
- Balloon fatigue in stent
- Catheter bond tensile strength
- Tip pull tensile
- Particulate evaluation

Biocompatibility

- Cytotoxicity
- Sensitization
- Irritation
- Acute systemic toxicity
- Material mediated pyrogenicity
- Hemocompatibility

Packaging

- Label, IFU, accessory integrity
- Packaging integrity

Animal Testing & Clinical Testing - Not Applicable.

After meeting all acceptance criteria, non-clinical testing has demonstrated that the Aperta NSE PTA is substantially equivalent to the predicate device. The non-clinical testing demonstrated that the difference between subject and predicate devices do not raise new questions of safety and effectiveness.