June 29, 2025

PendraCare
Erendira Rodriguez
Director of Quality Assurance and Regulatory Affairs
Van der Waalspark 20-22
Leek, 9351VC
Netherlands

Re: K250972
Trade/Device Name: Primum Hydrophilic Guiding Catheter
Regulation Number: 21 CFR 870.1250
Regulation Name: Percutaneous Catheter
Regulatory Class: Class II
Product Code: DQY
Dated: March 31, 2025
Received: March 31, 2025

Dear Erendira Rodriguez:

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,

Jenny R. Katsnelson -S

Digitally signed by Jenny R. Katsnelson -S
Date: 2025.06.29 23:22:10 -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)*
K250972

Device Name
Primum Hydrophilic Guiding Catheter

Indications for Use *(Describe)*
The Guiding Catheter is designed to provide a pathway through which therapeutic and diagnostic devices are introduced. The Guiding Catheter is intended to be used in the coronary or peripheral vascular system.

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) Summary

Per 21 CFR 807.92

A. Submitter information (807.92 (a) (1))

Prepared by:

Eréndira Rodríguez
Quality Assurance and Regulatory Affairs Director
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Manufacturer (510(k) Applicant)

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Date Prepared:

March, 2025

B. Device Name

Trade or proprietary name:	Primum Guiding Catheter
Common or usual name:	Percutaneous Catheter
Classification name:	Class II, 21 CFR 870.1250
Review Panel:	Cardiovascular
Product Code:	DQY

C. Predicate Device information

The legally marketed device which the 510(k) used for claiming equivalence are

- Convey 5F Guiding Catheters (K120585, August 8, 2012)
- Convey 6F Guiding Catheters (K120585, August 8, 2012)

PendraCare International B.V., Leek, The Netherlands, is the legal manufacturer of both the predicate device, Convey Guiding Catheter, and the submission subject device, the Primum Guiding Catheter. The Convey Guiding Catheter is a spin-off of the Primum Guiding Catheter, thus the products are identical with the only difference being the trade name.

D. Device Description

The Hydrophilic Guiding Catheter consists of a reinforced body with a hub and strain relief at the proximal end and an intermediate and soft tip at the distal end. The distal part of the catheter features a specific tip shape. A part of the catheter body features a hydrophilic coating. The (distal part of the) catheter body is provided either with or without "in-line" side holes.

The guiding catheter is a flexible plastic tube featuring a luer hub, strain relief, a body, an intermediate tip, and a soft tip. The body and the intermediate tip consist of an inner liner (basecoat) and an outer jacket (topcoat) reinforced with a tightly wound stainless steel braid wire in between the layers. The central lumen of the catheter is used for the percutaneous, transluminal passage and placement of guidewires, diagnostic and therapeutic devices within the vascular system. After the catheter is inserted through the skin using a dilator, a sheath (introducer) and guide wire is brought into position. Subsequently, a guidewire is advanced through its lumen and tracked over by a diagnostic device and/or a therapeutic devices to the intended location. The distal section of the catheters has a variety of preformed shapes (e.g. Judkins Left (abbreviated as JL), Judkins Right (JR), Amplatz
(AL), Multi-purpose (MP), hockey stick) to facilitate placement of the catheter tip in the desired target vessel. Some catheter models feature two (2) small "in-line" side holes in the intermediate tip section to maintain perfusion of the target vessel. This device is a single-use device (i.e., single patient, single procedure, single purpose use). After finalizing the procedure, the catheter is withdrawn, removed and discarded.

E. Intended use of Device

The Guiding Catheter is intended to provide a pathway through which therapeutic and diagnostic devices are introduced into the vascular system.

F. Indications for Use

The Guiding Catheter is designed to provide a pathway through which therapeutic and diagnostic devices are introduced. The Guiding Catheter is intended to be used in the coronary or peripheral vascular system.

G. Technological Characteristics / Substantial Equivalence

The Predicate device, Convey Guiding Catheter, is a spin-off of the Primum Guiding Catheter, with the only difference being the trade names. The products are identical in design, technical and biological specifications.

The Primum Guiding Catheters (5F, 6F, 7F and 8F) incorporate substantially equivalent device materials, packaging materials and design, intended use, fundamental technology (operating principle & mechanism of action), labeling and manufacturing processes, and sterilization process as those featured in the legally marketed predicated devices, the Convey 5F & 6F Guiding Catheters (K120585, August 8, 2012) and Convey 7F & 8F Guiding Catheters (K132197, July 11, 2013).

Device Characteristic	**New device**	**Primary Predicate**	**Reference**
Manufacturer	PendraCare International B.V.	PendraCare International B.V.	PendraCare International B.V.
Trade name device	**Primum** 5F, 6F, 7F and 8F Guiding Catheter K250972	**Convey** 5F, 6F Guiding Catheter K120585	**Convey** 7F, 8F Guiding Catheter K132197
Intended use/ Indications for Use	The Guiding Catheter is designed to provide a pathway through which therapeutic and diagnostic devices are introduced. The Guiding Catheter is intended to be used in the coronary or peripheral vascular system.	The Convey Guiding Catheter is designed to provide a pathway through which therapeutic and diagnostic devices are introduced. The Convey Guiding Catheter is intended to be used in the coronary or peripheral vascular system.	The Convey Guiding Catheter is designed to provide a pathway through which therapeutic and diagnostic devices are introduced. The Convey Guiding Catheter is intended to be used in the coronary or peripheral vascular system.

Operation Principle	Manually operated. Manual process.	Same	Same
Design/Construction	Hub, strain Relief, body, braiding wire between outer & inner body layer, Intermediate tip, Soft Tip, Side holes (optional), Hydrophilic coated body, uncoated body.	Same	Same
Materials	Hub Hub: 96.15% Grilamid TR55LX 3.85% Colorant white Hub Printing: Hot stamp foil Grey (5F) Hot stamp foil green (6F) Hot stamp foil Orange (7F) Hot stamp foil Blue (8F) Strain relief: 98% Grilamid L25 W40 2% Colorant white Body Base coat: 40% Vestamid L2140 40% Vestamid D16 20% Fusabond E204 Braiding: Flat rolled Stainless Steel 304V Top coat: 38% Vestamid L2140 35% Vestamid E62-S3 23% [Vestamid D16 (80%)+BiOCl (BironLF2000)(20%)] 4% Masterbatch colorant Blue (HT-MAB PA 51130) Coating (external): Primer – Hydrophilic Coating Intermediate tip-part-1* Base coat: 40% Vestamid L2140	Same	Same

	40% Vestamid D16 20% Fusabond E204 Braiding: Flat rolled Stainless steel 304V Intermediate tip material: 49% [40% Pebax 3533SA01 + 60% BiOCl] 49% Pebax 3533 SA01 2% Masterbatch colorant Blue (HT-MAB PA 51130) Intermediate tip Part-2* Filler Ring: 98% [40% Pebax 3533SA01 + 60% BiOCl] 2% Masterbatch colorant Blue (HT-MAB PA 51130) Braiding: Flat rolled Stainless steel 304V Intermediate tip material: 49% [40% Pebax 3533SA01 + 60% BiOCl] 49% Pebax 3533 SA01 2% Masterbatch colorant Blue (HT-MAB PA 51130) Soft tip: Polyether block-amide / Pebax 3533 SA01 (40%) BiOCl (60%) Packaging Materials Mounting card: 240 grs GZ (SBS) bleached carton Pouch: PET/PE Foil / Film, transparent • Top: 12 µm Laminated Polyester (PET) • Bottom: 50 µm Peelable		

	Polyethylene PE (96%) + 4% EVA, Tyvek® 1073B • uncoated Spunbonded non-woven polyethylene (HDPE) • natural white No printing Hang-tab: • Plastic sheet material PETG 635 µm • Adhesive: Hang-tite 203-A Box: Box (1) & Box (5), Box (5) 125cm: • 400/380/355 grams GC1 (or GC2) carton & white (or crème) back-layer • No Printing Labelling IFU: Woodfree Offset Paper, white, 70 grams – profijt Inner / Pouch Label (SB) Outer / Box Label (SB): Mactac's Velvet wood free coated paper, 1 X MP 196 acrylic adhesive emulsion Century 6 Inner/pouch & Outer/Box label Ink: Armor's Thermal Transfer Ribbon APR6, Wax/Resin, Black Carbon D1-547. End label: 80 gr flat wood free paper w/ permanent adhesive, white, no printing 85 gr flat wood free paper w/ permanent adhesive, white, no printing		

Package	Unit Pouch Shelf Box Shipping Carton	Same	Same
Specifications *	See **Dimension table** below.	Same	Same
Shelf life	3 years (36 months)	Same	Same
Disposable single use	Yes	Same	Same

*Specifications Dimension Table for Primum Guiding Catheter & Convey Guiding Catheter

Primum Guiding Catheter & Convey Guiding Catheter					
Dimension Table (Nominal) [mm]					
Description		**5F**	**6F**	**7F**	**8F**
A	**Soft Tip Length**	2	2	2	2
B	**Intermediate Tip Length**	15	15	15	15
C	**Distal Position First Side Hole**	n/a	27	27	27
D	**Distance between Side Holes**	n/a	4	4	4
E	**Hydrophilic Coating End Position, proximal from distal Tip**	17-87	17-87	17-87	17-87
F	**Hydrophilic Coating Start Position, proximal from distal Tip**	750	750	750	750
G	**Usable Catheter Length (90/100/125cm)**	900/1000	900/1000/1250	900/1000	900/1000
H	**Strain Relief Length**	25	25	25	25
I	**Total Length (90/100/125cm)**	972/1072	972/1072/1322	972/1072	972/1072
ØJ	**Side Hole Diameter**	n/a	0.77	0.77	0.94
ØOD	**Outer Diameter Body / Soft Tip**	≤1.82 / 1.89	≤2.11 / 2.20	≤2.46 / 2.54	≤2.78 / 2.87
ØID	**Inner Diameter Body, Hub / Soft Tip**	≥1.45 / 1.43	≥1.80 / 1.78	≥2.05 / 2.03	≥2.29 / 2.27

H. Summary biocompatibility and bench testing

The following biocompatibility tests were considered for the Primum Guiding Catheter considering the categorization of the Material Characterization for medical application per ISO 10993-1 and USP.

Categorization by Nature of body contact:

- External communicating device:
- Circulating blood: devices that contact circulating blood.

Categorization by Duration of Contact:

- Limited Exposure (A): Devices whose single or multiple use or contact is up to 24h.

ISO 10993-4: Haemocompatibility

- Hemolysis
- In vitro Haemocompatibility
- Coagulation Test Prothrombin Time Assay (PT)
- Coagulation Unactivated Partial Thromboplastic in Time Assay (UPTT)

ISO 10993-5: Cytotoxicity

ISO 10993-7: Ethylene Oxide Sterilization Residuals

ISO 10993-10:Sensitization

ISO 10993-10: Irritation/ Intracutaneous Reactivity

ISO 10993-11: Acute Systemic Toxicity

ISO 10993-11: Material Meditated Pyrogenicity

USP <661>: Packing Plastic containers leachables.

USP <85> Endotoxin-Mediated Pyrogenicity

The following in-vitro performances tests (following simulated use, if applicable) were considered for the Primum Guiding Catheters

- Shape Conformance (Shape retention)
- Inner Diameter
- Outer Diameter
- Catheter Usable Length
- Coating Length
- C-Kink (Bending Kink Diameter)
- Euler Kink (axial Kink Displacement)
- Radial Stiffness (Collapse)
- Coating Integrity (Visual Inspection)
- Outer Friction & Wear (Coating Integrity – functional tests)
- Three Point Bending Test (ending Stiffness Body)
- Pull Force (after simulated use)
- Radiopacity
- Torque Strength.
- Particulate Testing

I. Clinical and Nonclinical Performance Data and Conclusions

The Guiding Catheter is designed to provide a pathway through which therapeutic devices are introduced. The Guiding Catheter is intended to be used in the coronary or peripheral vascular system.

The only difference between the subject Device, Primum Guiding Catheter, and Predicate Device, Convey Guiding Catheter, is the trade name. Both devices are the same generation of guiding catheter developed by the manufacturer.

Therefore, the data presented in Convey 5F Guiding Catheters (K120585, August 8, 2012), Convey 6F Guiding Catheters (K120585, August 8, 2012), Convey 7F Guiding Catheters (K132197, July 11, 2013), and Convey 8F Guiding Catheters (K132197, July 11, 2013) on non-clinical design verification (bench) tests, design validation testing, as well as clinical post market surveillance (comparison) studies, including investigator-driven registries, and biocompatibility evaluation tests per ISO 10993-series of standards are all applicable to the Primum Guiding Catheter.

The data provided data for the FDA market clearances of the Predicate device, Convey Guiding Catheter, showed reasonable assurance that the proposed devices were designed and tested to assure conformance to the requirements for its intended use, which are the same data applicable to the Primum Guiding Catheter. No new safety or performance issues were raised during the testing.

J. Conclusion

The Primum Guiding Catheters are substantially equivalent to the Convey Guiding Catheters, which were cleared by FDA under premarket notifications K120585 (August 8, 2012) for 5F and 6F.