June 25, 2026

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

Re: K261242
Trade/Device Name: SimplGuide
Regulation Number: 21 CFR 870.1340
Regulation Name: Catheter Introducer
Regulatory Class: Class II
Product Code: DYB
Dated: April 15, 2026
Received: April 15, 2026

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 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, FINN E. DONALDSON -S

Digitally signed by FINN E. DONALDSON -S
Date: 2026.06.25 07:59:09 -04'00'

Finn Donaldson
Acting 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)*
K261242

Device Name
SimplGuide

Indications for Use *(Describe)*
The SimplGuide guiding sheath is indicated for the introduction of therapeutic and diagnostic devices into the peripheral and coronary vasculature through an access site.

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

Per 21 CFR 807.92

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

Prepared by:

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Date Prepared:

April 14, 2026

B. **Device Name**

Trade or proprietary name:	SimplGuide
Common or usual name:	Guiding Sheath
Classification name:	Class II, 21 CFR 870.1340
Review Panel:	Cardiovascular
Product Code:	DYB

C. **Predicate Device information**

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

- R2P Destination Slender Guiding Sheath (K193125) (Predicate device)
- Convey 7F Guiding Catheters (K132197, July 11, 2013) (Reference device)
- Primum Hydrophilic Guiding Catheter (K250972, June 29, 2025) (Reference device)

D. **Device Description**

Component 1: The SimplGuide guiding sheath (GS) consists of a reinforced body with a hub and strain relief at the proximal end and a radiopaque marker band and distal tip at the distal end. The distal part of the GS is straight without a shape. A part of the GS body features a hydrophilic coating. The GS is developed without side holes.
Component 2: The vessel dilator (VD) is supplied together with the GS. The combination GS and VD is introduced through the skin tissue into the vascular system of the patient, and advanced through the vasculature to the target location over a routinely used 0.035" guidewire.
The Design Inputs and Design Outputs are gathered in attachment 1 (Design Input – Design Output Table) per SOP R&D-006 (Design Input – Design Output).

E. **Intended use of Device**

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

F. **Indications for Use**

The SimplGuide guiding sheath is indicated for the introduction of therapeutic and diagnostic devices into the peripheral and coronary vasculature through an access site.

G. **Technological Characteristics / Substantial Equivalence**

See Comparison tables (Table 1 and Table 2) below.

Table 1: Comparison Predicate Device and Proposed Device

	Predicate Device	**New Proposed Device**
	R2P Destination Slender guiding sheath (6F) (K193125)	**SimplGuide guiding sheath (6F) (K261242)**
Product Code	**DYB (Introducer, catheter)**	**Same**
Trade Name	R2P™ Destination Slender™ Guiding Sheath	SimplGuide
Indications for use	R2P™ Destination Slender™ Guiding Sheath is indicated for the introduction of interventional and diagnostic devices into the human vasculature through an access site, including but not limited to the radial artery.	The SimplGuide guiding sheath is indicated for the introduction of therapeutic and diagnostic devices into the peripheral and coronary vasculature through an access site.
Operating Principle	Operated manually or by a manual process	Same
Design	Length: 75cm, 85cm, **95cm, 105cm**, 119cm and 149cm	Length: 100 cm
	ID: 2.2mm	ID: 2.10mm
	OD: 2.5mm	OD: 2.48mm
- *design / construction*	Sheath, Dilator, Hemostatic Valve with side tube and three-way stopcock	Sheath, Vessel Dilator
- *outer hydrophilic coating*	Yes	Yes
- *hydrophilic coating length*	Hydrophilic Coating: full usable length	Hydrophilic Coating: 75cm distal length
- *tip configuration*	Straight tip	Same
- *tip visibility material*	Radiopaque Tip: Nylon with Tungsten	Same
- *body reinforcement config*	Coiled reinforcement	Braided reinforcement
- *hub*	Nylon	Nylon Colorant
Vessel dilator	Vessel dilator included	Same
Vessel dilator extended length	5cm	Same
Hemostasis device	Hemostasis device: cross cut hemostatic valve, three way stopcock	No hemostasis device included
Materials	Inner layer: PTFE	Inner layer: PolyAmide/PolyEthylene blend
	Outer Layer: Nylon / polyether-blok-amide	Same

	Predicate Device	New Proposed Device
	R2P Destination Slender guiding sheath (6F) (K193125)	**SimplGuide guiding sheath (6F) (K261242)**
	Stainless steel reinforcement	Same
	Markerband Nylon with Tungsten	Same
- hydrophilic coating composition	Polyvinylpyrrolidone-based coating	Polyvinylpyrrolidone water-soluble polymer (hydrophilic coating) & primer
DILATOR	**Dilator Assembly** Tubing: Polypropylene. Hub: Polypropylene/Thermoplastic Elastomer. Blend Coating: Silicone Caulking Pin: Stainless steel.	**Dilator Assembly** Tubing: Pebax 7033 / Bismuth subcarbonate / Zinc stearate. Glue: Acrylate glue. Hub: Polycarbonate
Shelf-life	30 months	36 months
Sterility	Ethylene Oxide (validated in accordance with ANSI / AAMI / ISO 11135-1 to achieve SAL 10^{-6})	Same
Packaging	Unit Pouch; Shelf Box; Shipping Carton	Same

Table 2: Comparison Reference Device and Proposed Device

	Reference Device	New Proposed Device
	Convey Guiding Catheter (7F) (K132197) *Primum Hydrophilic Guiding Catheter (K250972)	**SimplGuide guiding sheath (6F) K261242**
Product Code	**DQY (Catheter percutaneous)**	**DYB (Introducer, catheter)**
Trade Name	Convey™ Guiding Catheter *Primum Hydrophilic Guiding Catheter	SimplGuide
Indications for use	The Convey Guiding/*Primum 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 SimplGuide guiding sheath is indicated for the introduction of therapeutic and diagnostic devices into the peripheral and coronary vasculature through an access site.
Operating Principle	Operated manually or by a manual process	Same
Design	Length: 100 cm	Same
	ID: 2.08mm	ID: 2.10mm
	OD: 2.37mm	OD: 2.48mm

	Reference Device	**New Proposed Device**
	Convey Guiding Catheter (7F) (K132197) ***Primum Hydrophilic Guiding Catheter (K250972)**	**SimplGuide guiding sheath (6F) K261242**
- design / construction	Catheter	Sheath, Vessel Dilator
- outer hydrophilic coating	Yes	Same
- hydrophilic coating length	Hydrophilic Coating Length: 75cm proximal of the intermediate tip	Hydrophilic Coating: 75cm distal length
- tip configuration	Only shaped tips	Straight tip
- tip visibility material	Radiopaque soft tip	Radiopaque Tip: Nylon with Tungsten
- body reinforcement config	Braided reinforcement	Same
- hub	Nylon Colorant	Same
Vessel dilator	No vessel dilator included	Vessel dilator included
Vessel dilator extended length	N.A.	5cm
Hemostasis device	No hemostasis device included	Same
Materials	Inner layer: PolyAmide/PolyEthylene blend	Same
	Outer Layer: Nylon / polyether-blok-amide	Same
	Stainless steel reinforcement	Same
	Bismuth oxychloride filled marker material	Markerband Nylon with Tungsten
- hydrophilic coating composition	Polyvinylpyrrolidone PVP water-soluble polymer (hydrophilic coating) & primer	Same
DILATOR	N/A	**Dilator Assembly** Tubing: Pebax 7033 / Bismuth subcarbonate / Zinc stearate. Glue: Acrylate glue. Hub: Polycarbonate
Shelf-life	36 months	Same
Sterility	Ethylene Oxide (validated in accordance with ANSI / AAMI / ISO 11135-1 to achieve SAL 10^{-6})	Same
Packaging	Unit Pouch; Shelf Box; Shipping Carton	Same

H. **Summary biocompatibility and bench testing**

The following biocompatibility tests were completed on the SimplGuide Guiding Sheath considering the categorization of the Material Characterization for medical application per ISO 10993-1 and USP.

ISO 10993-4: Hemocompatibility
- Hemolysis Test (Complete - Direct and Indirect Contact)
- Partial Thromboplastin Time (UPTT) Test – Direct Contact Method
- Complement Activation (C3 Complement Protein) Test – Indirect Contact Method
- Complement Activation (SC5b-9 (C5) Complement Protein) Test – Indirect Contact Method
- Platelet and Leukocyte Count (Direct Contact)

ISO 10993-5: Cytotoxicity
- L929 Minimal Essential Medium (MEM) Elution Test

ISO 10993-7: Ethylene Oxide Sterilization Residuals
- Simulated use: residue value after 24 hours at 37˚C by Gas chromatography.

ISO 10993-10: Sensitization
- Kligman Maximization Test – Normal Saline and Vegetable (Cottonseed) Oil Extracts

ISO 10993-10: Irritation/ Intracutaneous Reactivity
- Intracutaneous Injection Test – Normal Saline and Vegetable (Cottonseed) Oil Extracts

ISO 10993-11: Systemic toxicity
- Systemic Injection Test

ISO 10993-18: 2020 /Amd: 2023 Biological evaluation of medical devices - Part 18: Chemical characterization of materials
- Chemical characterization of the materials is performed.

ISO 10993-23: 2021 Biological evaluation of medical devices - Part 23: Test for irritation
- Intracutaneous Injection Test

USP <85> Endotoxin-Mediated Pyrogenicity
- LAL test.

The following in-vitro performances tests (following simulated use, if applicable) were completed of the SimplGuide Guiding Sheath:
- 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
- USP <788> Particulate testing (Light Obscuration after simulated use). Particle Count Test

I. Clinical and Nonclinical Performance Data and Conclusions

This 510(k) does not include data from clinical tests.
The User requirements were validated and concluded that it meets the Product Description and design for its intended purpose.

Performance testing was conducted to ensure that the SimplGuide Guiding Sheath met the applicable design and performance requirements during the shelf life, verify conformity to the applicable external and internal standards, and demonstrate substantial equivalence to the predicate device.

J. Conclusion

In summary, the PendraCare SimplGuide Guiding Sheath is substantially equivalent to its legally marketed predicate device, the R2P Destination Slender Guiding Sheath (K193125) with respect to the intended use, operating principles, fundamental design, catheter dimension, materials, technology, packaging, labeling and sterility.