



November 8, 2024

Pulnovo Medical (Wuxi) Co., Ltd
Wen Gu
Clinical Vice President
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Huishan Economic Dev Zone
Wuxi, Jiangsu 214000
China

Re: K242756

Trade/Device Name: Introducer Sheath (PFlexi00L065, PFlexi00L070, PFlexi00L075, PFlexi00L080, PFlexi00L090, PFlexi30L065, PFlexi30L070, PFlexi30L075, PFlexi30L080, PFlexi30L090, PFlexi45L065, PFlexi45L070, PFlexi45L075, PFlexi45L080, PFlexi45L090, PFlexi60L065, PFlexi60L070, PFlexi60L075, PFlexi60L080, PFlexi60L090)

Regulation Number: 21 CFR 870.1340

Regulation Name: Catheter introducer

Regulatory Class: Class II

Product Code: DYB

Dated: September 12, 2024

Received: September 12, 2024

Dear Wen Gu:

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,

Sevan R. Oungoulian -S 2024.11.08 16:59:04 -05'00'

For

Finn Donaldson

Assistant Director (Acting)

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

Indications for Use

510(k) Number (if known)
K242756

Device Name

Introducer Sheath (PFlexi00L065, PFlexi00L070, PFlexi00L075, PFlexi00L080, PFlexi00L090, PFlexi30L065, PFlexi30L070, PFlexi30L075, PFlexi30L080, PFlexi30L090, PFlexi45L065, PFlexi45L070, PFlexi45L075, PFlexi45L080, PFlexi45L090, PFlexi60L065, PFlexi60L070, PFlexi60L075, PFlexi60L080, PFlexi60L090)

Indications for Use (Describe)

The Introducer Sheath is intended for the introduction of diagnostic and therapeutic devices into the human vasculature, including but not limited to intracardiac, renal or other peripheral placements.

Do not use this device for neural placements.

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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Summary

I Submitter

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Prepared for:

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Contact person:

Name: Mr. Wen Gu
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Tel.: +86-18906178526
E-mail: ra@pulnovomed.com

Preparation date: September 12, 2024

II Proposed Device

Trade Name of Device: Introducer Sheath
Models: PFlexi00L065, PFlexi00L070, PFlexi00L075, PFlexi00L080, PFlexi00L090, PFlexi30L065, PFlexi30L070, PFlexi30L075, PFlexi30L080, PFlexi30L090, PFlexi45L065, PFlexi45L070, PFlexi45L075, PFlexi45L080, PFlexi45L090, PFlexi60L065, PFlexi60L070, PFlexi60L075, PFlexi60L080, PFlexi60L090
Regulation name: Catheter introducer
Regulation Number: 21 CFR 870.1340
Regulatory Class: Class II
Product code: DYB
Review Panel: Cardiovascular

III Predicate Device

Predicate device

510(k) Number: K210627
Product Code: DYB

Classification: 21 CFR 870.1340

Trade Name: Breezeway II

Regulatory Class: II

Reference Device

510(k) Number: K172995

Product Code: DYB

Classification: 21 CFR 870.1340

Trade Name: Destination Carotid Guiding Sheath, Destination Peripheral Guiding Sheath, Destination Renal Guiding Sheath

Regulatory Class: II

IV Device description

The Introducer Sheath is intended for establishing a percutaneous access that facilitates the introduction of intravascular devices. The Introducer Sheath is composed of the Guiding Sheath and the Dilator. The Introducer Sheath is available in multiple effective lengths and curve shape configurations.

Principles of Operation

The Introducer Sheath is used to assist in the insertion of diagnostic/therapeutic instruments such as guide wires, catheters, and other medical devices into blood vessels, or to establish percutaneous access pathways that facilitate the insertion of intravascular instruments.

V Indications for use

The Introducer Sheath is intended for the introduction of diagnostic and therapeutic devices into the human vasculature, including but not limited to intracardiac, renal or other peripheral placements.

Do not use this device for neural placements.

VI Comparison of technological characteristics with the predicate device

The comparable properties between the proposed device and the predicate devices are listed in Table 1. Table 1 compares the Introducer Sheath to the predicate devices with respect to intended use, technological characteristics, and principles of operations, providing more detailed information regarding the bases for the determination of substantial equivalence.

Table 1 Comparison of technological characteristics with the predicate device

Items	Proposed Device	Predicate Device	Reference Device
Device name	Introducer Sheath	Breezeway II	Destination® Guiding Sheath (Carotid, Peripheral and Renal)
Regulatory Decision	/	K210627	K172995
Product Code	DYB	DYB	DYB
Regulation Number	870.1340	870.1340	870.1340
Intended Use/Indications for use	<p>The Introducer Sheath is intended for the introduction of diagnostic and therapeutic devices into the human vasculature, including but not limited to intracardiac, renal or other peripheral placements.</p> <p>Do not use this device for neural placements.</p>	<p>The Breezeway II products are intended for the introduction of diagnostic and therapeutic devices into the human vasculature, including but not limited to intracardiac, renal or other peripheral placements.</p> <p>Do not use this device for neural placements.</p>	<p>The Destination® Carotid Guiding Sheath is designed to be used for the introduction of interventional and diagnostic devices into the human vasculature, including but not limited to the carotid arteries.</p> <p>The Destination® Peripheral Guiding Sheath is designed to be used for the introduction of interventional and diagnostic devices into the human vasculature, including but not limited to lower extremity access via a contralateral approach.</p> <p>The Destination® Renal Guiding Sheath is intended for the introduction of interventional and diagnostic devices into the human vasculature including but not limited to</p>

			the renal arteries.
Operation Principle	Operated manually or by a manual process	Operated manually or by a manual process	Operated manually or by a manual process
Design / Construction	Sheath, Dilator, Hemostatic Valve with side tube and three-way stopcock	Sheath, Dilator, Hemostatic Valve with side tube and three-way stopcock	Sheath, Dilator, Hemostatic Valve with side tube and three-way stopcock, and Dilator Retaining Clip
Materials	<p>Sheath Assembly</p> <p>Tubing: PTFE-SSL braided-Pebax, BaSO₄</p> <p>Tip: Pebax, BaSO₄</p> <p>Hydrophilic Coating: NA</p> <p>Radiopaque Band: Platinum-Iridium alloy</p> <p>Dilator Assembly</p> <p>Tubing: HDPE, BaSO₄</p> <p>Hub: HDPE</p> <p>Hemostatic Valve Assembly</p> <p>Valve assembly: Nylon, silicone rubber, Polyurethane</p> <p>Side Tube/3-Way Stopcock Assembly: Polyvinyl chloride, Polycarbonate, Polyethylene</p>	<p>Sheath</p> <p>Liner (Inner): PA12</p> <p>Distal Tip (Outer): Pebax 45D</p> <p>Proximal Shaft (Outer): Pebax 63D</p> <p>Sheath Hub Cap: Polycarbonate</p> <p>Sheath Coating: Hydrophobic</p> <p>Hemostatic Valve: Silicone</p> <p>Marker Band: Gold</p> <p>Dilator</p> <p>6F to 12F: HDPE (Body and Hub)</p> <p>14F: LDPE (Body), HDPE (Hub)</p>	<p>Sheath Assembly</p> <p>Tubing: PTFE-SSL coil-Nylon</p> <p>Tip: Nylon</p> <p>Hydrophilic Coating: Polyvinylpyrrolidone-based Coating</p> <p>Hub: Nylon</p> <p>Radiopaque Band: Gold</p> <p>Dilator Assembly</p> <p>Tubing: Polypropylene/Thermoplastic Elastomer Blend</p> <p>Hub: Polypropylene</p> <p>Coating: Reactive Silicone</p> <p>Caulking pin: Stainless Steel</p> <p>Tuopy-Borst Valve (TBV):</p> <p>Y-Connector Assembly: Polycarbonate, Silicone</p> <p>Side Tube/3-Way Stopcock Assembly: Polycarbonate, Polybutadiene, High Density Polyethylene, Base Resin and HDPE colorants, Polypropylene</p> <p>Cross Cut Valve (CCV):</p>

			Valve assembly: Polypropylene, Polycarbonate, Silicone Rubber, Elastomer, Non-reactive silicone oil 1000cst Side Tube/3-Way Stopcock Assembly: Same as TBV
Package	Unit Pouch Shelf Box Shipping Carton	Unit Pouch Shelf Box Shipping Carton	Unit Pouch Shelf Box Shipping Carton
Specifications	Sheath Size: 9Fr Sheath Length: 65-90cm Hydrophilic Coating: NA Curve Shapes: ST, MP Dilator Extended Length: 2.5cm	Sheath Size: 6Fr to 14 Fr Sheath Length 79 cm (6Fr to 14 Fr) 110 cm (6Fr to 10Fr) Hydrophilic Coating: Hydrophobic Curve Shapes: Not reported Dilator Extended Length: Not reported	Sheath Size Carotid: 6-7Fr Peripheral: 5-8Fr Renal: 5-7Fr Sheath Length Carotid: 80-110cm Peripheral: 45-110cm Renal: 45-55cm Hydrophilic Coating Carotid Distal 15 cm Peripheral Distal 15-60 cm Renal Distal 5 cm Curve Shapes Carotid: ST, MP Peripheral: ST Renal: ST, HS, MP, RDC, LIMA Dilator Extended Length Carotid: 5cm Peripheral: 2.5 and 5cm Renal: 2cm
Sterilization	Ethylene Oxide	Ethylene Oxide	Ethylene Oxide
Shelf life	24 months	36 months	6 months
Disposable Single Use	Yes	Yes	Yes

VII Performance Data

Non-Clinical Bench Performance Testing

Performance tests were conducted to ensure that the Introducer Sheath met the applicable design and performance requirements throughout its shelf life. The physical properties (including particulate matter), chemical properties, microbial properties, sterile barrier properties, biocompatibility, shelf-life, packaging, simulated transportation and labeling and identification of the Introducer Sheath products were tested to ensure the design output meets the requirements of the design inputs. The tests results indicate that the Introducer Sheath passed all the tests and it conforms to *ISO 11070:2014 Sterile single-use intravascular introducers, dilators and guidewires*. The basis for a determination of substantial equivalence of the device is demonstrated by the following:

Physical properties

1. Dilator:

- Appearance,
- Dimensional (including OD/ID, working length),
- Luer compatibility,
- Guidewire compatibility,
- Tensile strength.

2. Introducer sheath:

- Appearance,
- Dimensional (including OD/ID, working length, curve geometry),
- Luer compatibility,
- Guidewire compatibility,
- Valve liquid/air leak test,
- Tensile strength,
- Torque strength,
- Simulated use,
- Kink resistance,
- Particulate matter,
- Radiopacity.

Biocompatibility

The Introducer Sheath was evaluated for biological safety based on its body contact and duration per ISO 10993-1 and FDA Guidance on Use of International Standard ISO 10993-1.

The Introducer Sheath is classified as an Externally Communicating Medical Device with limited (<24 hours) direct contact with patients' circulating blood.

The following tests are recommended by FDA and ISO 10993-1 to be performed for this device classification:

3. Cytotoxicity
4. Sensitization
5. Irritation
6. Acute Systemic & Pyrogenicity
7. Hemocompatibility

Sterilization

The sterility of the device is assured using a sterilization method validated in accordance with ISO 11135:2014, *Sterilization of health-care products - Ethylene oxide - Requirements for the development, validation and routine control of a sterilization process for medical devices*.

The sterilization process was validated utilizing the overkill half cycle approach to provide a Sterility Assurance Level (SAL) of 10^{-6} .

Introducer Sheath is a limited exposure device. After 24 hours of heated aeration, the level of residual ethylene oxide (EO) and ethylene chlorohydrin (ECH) do not exceed an average daily dose of 4 mg and 9 mg respectively per ISO 10993-7:2008.

VIII Clinical Testing

No clinical study is included in this submission.

IX Conclusion

Based on the similarity of the subject and predicate devices in terms of the intended use, principle of operation and overall technological characteristics, and the results of the conducted tests, the Pulnovo Medical (Wuxi) Co., Ltd. Introducer Sheath is substantially equivalent to the predicate device.