July 28, 2023

Neptune Medical, Inc.
% Eric Bannon
Regulatory Consultant
Alvamed, Inc.
935 Great Plain Ave, Suite 166
Needham, MA 02492

Re: K230801
Trade/Device Name: Pathfinder Endoscope Overtube with Balloon Device
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope And Accessories
Regulatory Class: Class II
Product Code: FED
Dated: June 28, 2023
Received: June 29, 2023

Dear Eric Bannon:

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 (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 located 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.

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 803) for devices or postmarketing safety reporting (21 CFR 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 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 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,

Shanil P. Haugen -S

Shanil P. Haugen, Ph.D.
Assistant Director
DHT3A: Division of Renal, Gastrointestinal,
Obesity and Transplant Devices
OHT3: Office of GastroRenal, ObGyn,
General Hospital and Urology 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: 06/30/2023
*See PRA Statement below.*

510(k) Number *(if known)*

K230801

Device Name
Pathfinder Endoscope Overtube with Balloon

Indications for Use *(Describe)*
The Pathfinder Endoscope Overtube with Balloon is intended to be used with an endoscope to facilitate intubation, change of endoscopes, and treatment in the gastrointestinal (GI) tract in adult patients (22 years of age and older).

Type of Use *(Select one or both, as applicable)*

X 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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*"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."*

## 1.0 510(K) SUMMARY

1.1 Name and Address of Owner/Submitter

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1.2 Correspondent/Primary Contact Person

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1.3 Submission Information

| | |
|---|---|
| Date Summary Prepared: | March 22, 2023 |
| Name of Device: | Pathfinder Endoscope Overtube with Balloon |
| Device Classification Name: | Endoscope and Accessories |
| Common or Usual Name: | Endoscope Accessory Overtube |
| Classification: | Class II |
| Product Code: | FED (21 CFR 876.1500) |
| Predicate Device: | Pathfinder Endoscope Overtube (K211301) |
| Reference Device: | Dilumen Endolumenal Interventional Platform (K210851) |

1.4 Predicate/Reference Device

| | 510(k) Number | Code | Device Name | Submitter Name |
|---|---|---|---|---|
| **Predicate Device** | K211301 | FED | Pathfinder Endoscope Overtube | Neptune Medical, Inc. |
| **Reference Device** | K210851 | FDF | Dilumen Endolumenal Interventional Platform | Lumendi |

1.5 Device Description

The Pathfinder Endoscope Overtube with Balloon device consists of a hollow tube with a balloon at the distal end for use over a flexible gastrointestinal endoscope. The purpose of the balloon is to contact the lumen walls to provide stabilization to the distal end of the overtube within the GI tract. The endoscope is inserted through the proximal end of the device and comes out the distal end. The free space between the overtube and the endoscope is lubricated with water through the irrigation line by connecting to the irrigation/water Luer (female Luer lock fitting) and injecting water. The vacuum line is connected to free space within the device and is completely contained. A source of vacuum must be connected to the barb fitting per the diagram below for the overtube to transition between the flexible and rigid conditions. The balloon line is connected to an extrusion within the device that creates an air pathway from handle to the balloon. An inflation device must be connected to the Luer (male Luer lock fitting) to inflate and/or deflate the balloon. The handle rotator has two positions. The first position connects the device to atmosphere (vent) to stay in the flexible condition. The second position connects the device to a source of vacuum to transition to the rigid condition. When transitioned to the rigid condition, the device maintains its shape at the time of rigidization, allowing the endoscope to advance or withdraw relative to the overtube with minimal disturbance to surrounding anatomy. Balloon inflation and deflation are actuated and controlled by an existing balloon controller unit within the endoscopy suite. The device must be connected to the balloon controller to transition into the inflated and deflated condition.

1.6 Comparison of Subject Predicate, and Reference Device

**Table 1.6:** Comparison of Predicate/Reference Device to Subject Device

| | **Subject Device:**<br>**Pathfinder Endoscope Overtube with Balloon** | **Predicate Device:**<br>**Pathfinder Endoscope Overtube** | **Reference Device:**<br>**Dilumen Endoluminal Interventional Platform** |
|---|---|---|---|
| **510(k) Number** | TBD | K211301 | K210851 |
| **510(k) Submitter/ Holder** | Same as predicate | Neptune Medical, Inc. | Lumendi |
| **Regulation Code** | Same as predicate | FED | FDF |
| **Regulation Number** | Same as predicate/ reference | 876.1500 | 876.1500 |

| | | | |
|---|---|---|---|
| **Common Name** | Same as predicate | Endoscope Access Overtube, Gastroenterology-urology | Colonoscope and accessories, flexible/rigid |
| **Regulation Description** | Same as predicate/ reference | Endoscope and accessories | Endoscope and accessories |
| **Device Classification** | Same as predicate/ reference | Class II | Class II |
| **Indications for Use** | The Pathfinder Endoscope Overtube with Balloon is intended to be used with an endoscope to facilitate intubation, change of endoscopes, and treatment in the gastrointestinal (GI) tract in adult patients (22 years of age and older). | The Pathfinder Endoscope Overtube is intended to be used with an endoscope to facilitate intubation, change of endoscopes, and treatment in the gastrointestinal (GI) tract in adult patients (22 years of age and older) | The Lumendi DiLumen is an accessory to an endoscope. The DiLumen dual balloon accessory is intended for use with any standard endoscope that has a distal tip outer diameter of 12.5 – 14.3 mm. The device is indicated to ensure complete positioning of an endoscope during navigation in the large intestine, while assisting with optical visualization, diagnosis, tissue manipulation, and endoscopic treatment. |
| **Intended Population** | Same as predicate | Adult patients undergoing gastrointestinal endoscopy | Not Available |
| **Sterilization Method** | Same as predicate | Ethylene Oxide (EO) Sterilization | Non-Sterile |
| **Single Use** | Yes | Yes | Yes |
| **Device Technology** | Vacuum-assisted rigidizing overtube with balloon for endoscopic procedures in the GI Tract. | Vacuum-assisted rigidizing overtube for endoscopic procedures in the GI Tract. | The DiLumen utilizes two balloons to position and stabilize the endoscope within a patient's large intestine. After the DiLumen is installed over the endoscope, the endoscope and DiLumen are navigated to the target |

| | | | |
|---|---|---|---|
| | | | zone with the balloons deflated. |
| **Dimensions** | Two Sizes, with total length of 85cm and 110cm. With nominal inner diameter of 14mm. Nominal balloon outer diameter of 40mm. | Nine sizes, with total length from 65 cm to 145 cm. With nominal inner diameter of 11mm to 16 mm. | Fore and aft balloon outer diameter: 60mm<br>Fore inner diameter: 17.6mm Working length: 168 cm, 130 cm, 103 cm |

1.7 Environment of Use, and Contraindications

The intended environment of use for the Pathfinder Endoscope Overtube with Balloon Device is the Gastrointestinal tract.

The contraindications are patients with esophageal bleeding, lesion(s), and/or laceration; esophageal strictures and/or varices; laryngeal perforation; trauma to teeth, gums, and/or pharynx; aspiration pneumonia; or any other condition that may preclude endoscopy.

1.8 Performance Data: Summary of Functional and Performance Testing

The following Functional and Performance Bench has been completed:

- Simulated use testing
- Lubricity
- Insufflation
- Insertion/Removal
- Navigation
- Rigidization/De-Rigidization
- Endoscope Compatibility
- Balloon Reliability
- Balloon Pressure Stability
- Balloon Inflation/Deflation
- Balloon dimensions

1.9 Performance Data: Summary of Biocompatibility Testing

The biocompatibility evaluation for the Pathfinder Endoscope Overtube with Balloon device was conducted in accordance with the guidance document “Use of International Standard ISO 10993-1, ‘Biological Evaluation of Medical Devices Part 1: Evaluation and Testing Within a Risk Management

Process,'" June 16, 2016, and International Standard ISO 10993-1 "Biological Evaluation of Medical Devices – Part 1: Evaluation and Testing Within a Risk Management Process," as recognized by FDA and other applicable standards. The testing included the following:

- Cytotoxicity
- Sensitization
- Irritation
- Systemic Toxicity
- Material Mediated Pyrogenicity

The Pathfinder Endoscope Overtube with Balloon Device is considered to contact breached or compromised surfaces for a duration of less than 24 hours.

1.10 Performance Data: Summary of Clinical Testing

No clinical testing was applicable to this submission.

1.11 Conclusions

Like the predicate originally cleared by the FDA, the modified Pathfinder Endoscope Overtube with Balloon Device has been shown to be safe through performance testing. Design changes made to the device do not raise any questions of safety or effectiveness. Verification and validation data support substantial equivalence of the modified Pathfinder Endoscope Overtube with Balloon Device to the legally marketed predicate device.