May 28, 2021

Neptune Medical, Inc.
% Ian Broome, M.S.
Regulatory Consultant
AlvaMed, Inc.
935 Great Plain Ave, Ste. 166
Needham, MA 02492

Re: K211301
Trade/Device Name: Pathfinder Endoscope Overtube
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope and accessories
Regulatory Class: Class II
Product Code: FED
Dated: April 28, 2021
Received: April 29, 2021

Dear Ian Broome:

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, 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)*
K211301

Device Name
Pathfinder Endoscope Overtube

Indications for Use *(Describe)*
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).

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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1.0 SPECIAL 510(K) SUMMARY

This Special 510(k) for the Pathfinder Endoscope Overtube is submitted based on the FDA Guidance document "The Special 510(k) Program: Guidance for Industry and Food and Drug Administration Staff" (issued September 13, 2019).

1.1 Name and Address of Owner/Sponsor

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1.2 Correspondent/Primary Contact Person

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1.3 Submission Information

Date Summary Prepared:	May 20, 2021
Name of Device:	Pathfinder Endoscope Overtube
Device Classification Name:	Endoscope and Accessories
Common or Usual Name:	Endoscopic Access Overtube
Classification:	Class II
Product Code:	FED (21 CFR 876.1500)
Predicate Device:	Pathfinder Endoscope Overtube (K191415)

1.4 Device Description

The Pathfinder Endoscope Overtube (Pathfinder) device consists of a flexible overtube that may be connected to vacuum for rigidization. It is used with an endoscope for procedures in the gastrointestinal tract. The handle includes a vacuum line which is connected to free space within the device that is completely contained, forming the vacuumable volume. The handle rotator has two positions: the first connects the vacuumable volume within the device to atmosphere (vent) to stay in the flexible position, and the second position connects the vacuumable volume 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 the surrounding anatomy. When transitioned to the flexible

condition, the device is able to move relative to the patient anatomy and endoscope for navigation through the GI tract. The device is provided sterile (EO). After use, the device is discarded and disposed of in accordance with local regulations.

There are no associated device accessories included as a part of this submission.

1.5 Indications for Use

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).

1.6 Comparison of Manufacturer's Cleared Device and Modified Device

Table 1. Comparison of Modified Device to Cleared Device

	Subject **Pathfinder Endoscope Overtube (Gen. 2.0)**	**Predicate Device** **Pathfinder Endoscope Overtube (Gen. 1.0)**
510(k) Number	K211301	K191415
510k Submitter/Holder	Same as predicate	Neptune Medical, Inc.
Product Code	Same as predicate	FED
Regulation No.	Same as predicate	876.1500
Regulation Description	Same as predicate	Endoscope and accessories.
Common Name	Same as predicate	Endoscopic Access Overtube, Gastroenterology-urology
Indications for Use	Same as predicate	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).
Sterility	Same as predicate	Ethylene Oxide (EO) Sterilization
Single-Use	Same as predicate	Yes
Device Technology	Same as predicate	Vacuum-assisted rigidizing overtube for endoscopic procedures in the GI Tract.
Dimensions	Nine sizes, from 65 to 145 cm long and 11 to 16 mm inner diameter.	One size, 85 cm long and 14 mm inner diameter.

1.7 Summary of Modification

The primary modification being addressed by this submission is the creation of eight new sizes of Pathfinder Endoscope Overtube of various combinations of three different diameters and four different lengths.

The durometer of the vacuum and irrigation line material was increased. Lastly, additional modifications to labeling driven by the new sizes and/or clinical feedback on the earlier device are included in this submission.

Table 2. New Sizes, Compared with Original Size Cleared in K191415

REF (Catalog Number)	*Description*	*Inner Diameter (mm)*	*Length (cm)*
GI 065110-2	Pathfinder® Endoscope Overtube, 11 mm ID x 65 cm Length	11	65
GI 085110-2	Pathfinder® Endoscope Overtube, 11 mm ID x 85 cm Length		85
GI 145110-2	Pathfinder® Endoscope Overtube, 11 mm ID x 145 cm Length		145
GI 065140-2	Pathfinder® Endoscope Overtube, 14 mm ID x 65 cm Length	14	65
GI 085140-2 **(original size)**	Pathfinder® Endoscope Overtube, 14 mm ID x 85 cm Length		85
GI 110140-2	Pathfinder® Endoscope Overtube, 14 mm ID x 110 cm Length		110
GI 065160-2	Pathfinder® Endoscope Overtube, 16 mm ID x 65 cm Length	16	65
GI 085160-2	Pathfinder® Endoscope Overtube, 16 mm ID x 85 cm Length		85
GI 110160-2	Pathfinder® Endoscope Overtube, 16 mm ID x 110 cm Length		110

1.8 Summary of Functional and Performance Testing

The line extension was the subject of extensive testing under applicable design control requirements, including:

- Lubricity
- Insufflation
- Insertion/Removal
- Navigation
- Rigidization/De-Rigidization
- Dimensional Measurements
- Endoscope Compatibility

1.9 Summary of Clinical Testing

No clinical testing was applicable to this submission.

1.10 Conclusion

Like the predicate first-generation device originally cleared by the FDA, the modified Pathfinder Endoscope Overtube has been shown to be safe through bench testing. Design changes made to the device do not raise any unanswered questions of safety or effectiveness. Test data support substantial equivalence of the modified Pathfinder to the legally marketed predicate device.