August 30, 2019

Neptune Medical, Inc.
% Ian Broome, M.S.
Consultant
AlvaMed, Inc.
935 Great Plain Avenue, #166
Needham, MA 02492

Re: K191415
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: August 15, 2019
Received: August 16, 2019

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,

for
Martha Betz, Ph.D.
Acting Assistant Division 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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K191415

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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5.0 TRADITIONAL 510(K) SUMMARY FOR PATHFINDER™ ENDOSCOPE OVERTUBE DEVICE

I. SUBMITTER

Neptune Medical, Inc.

1828 El Camino Real, Suite 508

Burlingame, CA 94010

Phone: (617) 517-4932

Fax: (617) 249-0955

Contact Person: Ian Broome, AlvaMed, Inc.

Date Prepared: August 28, 2019

II. DEVICE

Name of Device: Pathfinder™ Endoscope Overtube (Model GI 085140)

Common or Usual Name: Endoscopic Access Overtube

Classification Name: Endoscope and accessories (21 CFR 876.1500)

Regulatory Class: II

Product Code: FED

III. PREDICATE DEVICE

KMS Medical EndoGuide (K063654)

IV. DEVICE DESCRIPTION

The Pathfinder™ Endoscope Overtube (Pathfinder™) device consists of a flexible overtube that may be connected to vacuum for rigidization via an attached stopcock and is used with an endoscope for procedures in the gastrointestinal tract. The stopcock is connected to the vacuum line which is connected to free space within the device and is completely contained, forming the vacuumable volume. The stopcock has two positions: the first position connects the vacuumable volume within the device to atmosphere (vent) to stay in the flexible condition, and 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. 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.

V. 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).

The Indications for Use statement for the Pathfinder™ Endoscope Overtube device above is similar to the predicate device; any differences do not alter the intended therapeutic use of the device nor do they affect the safety and effectiveness of the device relative to the predicate. Both the subject and predicate devices have the same intended use for endoscopic treatment in the GI tract.

The table below provides an overview of the intended patient population, environment of use, and contraindications.

Intended Population, Environment of Use, and Contraindications

Intended Population:	Adults (≥ 22 years old) requiring gastrointestinal endoscopic treatment
Intended Environment of Use:	Gastrointestinal tract
Contraindications:	Those who have had extensive abdominal surgeries may be poor candidates because of adhesions or altered anatomy. Use contraindicated in 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.

VI. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE

	Subject Device: **Pathfinder™ Endoscope Overtube**	**Predicate Device:** **KMS EndoGuide**
Manufacturer	Neptune Medical, Inc.	KMS Medical, LLC
510(k) Number	(to be determined)	K063654
Product Code	FED	FDF, subsequently FED
Regulation Number	21 CFR 876.1500	21 CFR 876.1500
Regulation Description	Endoscope and accessories.	Endoscope and accessories.
Common Name	Endoscopic Access Overtube, Gastroenterology-urology	Colonoscope and Accessories, Flexible/Rigid
Intended 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).	The EndoGuide is intended to be used with an endoscope to facilitate intubation, change of endoscopes and removal of multiple polyps and/or foreign bodies.
Sterility	Ethylene Oxide (EO) Sterilization	Unknown, believed to be EO
Single-Use	Yes	Yes

	Subject Device: **Pathfinder™ Endoscope Overtube**	**Predicate Device:** **KMS EndoGuide**
Design Characteristics	• Vacuum-assisted rigidizing overtube for endoscopic procedures in the GI Tract • Internal wire-reinforced member	• Vacuum-assisted rigidizing overtube for endoscopic procedures in the GI Tract • Internal wire-reinforced member

Both devices are intended as assistive aids to the medical practitioner for endoscopic treatment in the GI tract.

The subject and predicate devices are based on the following same technological elements:

- an internal wire-reinforced member to the device;
- switchable vacuum-based rigidization/de-rigidization; and
- dimensions and design characteristics intended for use with pediatric endoscopes.

VII. PERFORMANCE DATA

The following performance data are provided in support of the substantial equivalence determination.

Biocompatibility Testing

The biocompatibility evaluation for the Pathfinder™ 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 battery of testing included the following tests:

- Cytotoxicity
- Sensitization
- Irritation
- Systemic Toxicity
- Pyrogenicity

The Pathfinder™ is considered to contact breached or compromised surfaces for a duration of less than 24 hours.

Mechanical Testing

- Simulated use testing
- Lubricity
- Insufflation
- Insertion/Removal
- Steering
- Navigation
- Rigidization/De-Rigidization
- Endoscope Compatibility

VIII. CONCLUSIONS

The non-clinical data support the safety of the device and the hardware verification and validation demonstrate that the Pathfinder™ shall perform as intended in the specified use conditions. The data demonstrate that the Pathfinder™ performs comparably to the predicate device currently marketed for the same intended use.