May 25, 2021

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

Re: K210915
Trade/Device Name: Pathfinder Endoscope Cap
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope and accessories
Regulatory Class: Class II
Product Code: FDS, FDF, FTY
Dated: March 26, 2021
Received: March 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)*
K210915

Device Name
Pathfinder Endoscope Cap

Indications for Use *(Describe)*
The Pathfinder Endoscope Cap is intended to be used in combination with compatible endoscopes to maintain the field of view during endoscopic procedures such as mucosal resection.

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.

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1.0 TRADITIONAL 510(K) SUMMARY FOR PATHFINDER® ENDOSCOPE CAP

1.1 Name and Address of Submitter

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1.2 Correspondent/Primary Contact Person

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1.3 Date Summary Prepared

March 26, 2021

1.4 Predicate Device

FUJIFILM Hood Models DH-28GR, DH-29CR and DH-30CR (K162749)

1.5 Device Description

The Pathfinder Endoscope Cap is single-use distal attachment for endoscopes. It is an aid to endoscopic visualization and treatment in the gastrointestinal (GI) tract. The Pathfinder Endoscope Cap consists of a single piece of Pebax® in a symmetrical, tapering shape for placement on the distal tip of an endoscope. It is a short, transparent tube with an attaching portion used to connect the cap to an applicable endoscope, a distal portion that tapers into a narrower diameter opening, and a side hole for drainage to prevent fluids lodging on the surface of the endoscope. The device is intended to be used in combination with compatible endoscopes to maintain the field of view during endoscopic procedures such as mucosal resection in the GI tract.

The Pathfinder Endoscope Cap has the following physical and performance characteristics:

- Sterilized by ethylene oxide
- For single use
- Tapering distal tip
- Soft stop (tactile indicator of correct depth position)

- Compatible with endoscopes with 11.7 mm outer diameter distal ends, such as the Olympus PCF-H180A and PCF-H190
- Compatible with the Pathfinder Endoscope Overtube, which is intended for use with the same size endoscopes.

1.6 Comparison of Predicate Device and Subject Device

	Subject Device: Pathfinder Endoscope Cap	**Predicate Device: FUJIFILM Hood Models DH-28GR, DH-29CR and DH-30CR**
K Number	K210915	K162749
Manufacturer	Neptune Medical, Inc.	Fujifilm Medical Systems USA, Inc.
Device Trade Name	Pathfinder Endoscope Cap	FUJIFILM Hood Models DH-28GR, DH-29CR and DH-30CR
Catalog Number/Ref	GI EC-0412-1	DH-28GR, DH-29CR and DH-30CR
Common Name	Endoscope distal attachment (cap/hood) and Measuring Tape	Endoscope distal attachment (cap/hood)
Regulation Number	21 CFR 876.1500 and 878.4800	21 CFR 876.1500
Regulation Description	Endoscope and accessories; Manual surgical instruments for general use	Endoscope and accessories
Product Code	FDS, FDF, FTY	FDS, FDF
Device Class	Class II and Class I	Class II
Device Panel	78, Gastroenterology and Urology	78, Gastroenterology and Urology
Indications for Use	The Pathfinder Endoscope Cap is intended to be used in combination with compatible endoscopes to maintain the field of view during endoscopic procedures such as mucosal resection.	The FUJIFILM Hood Models DH-28GR, DH-29CR and DH-30CR are intended to be used in combination with compatible endoscopes to maintain the field of view during endoscopic procedures such as mucosal resection.
Sterilization Method	Ethylene Oxide	Ethylene Oxide
Single Use or Reusable	Single use	Single use
Materials	Pebax®	Silicone
Outer diameter	12.04 mm	11.8-14.8 mm
Inner diameter of distal end	9.76 mm	8.0 mm
Total length	8.05 mm	17.0 mm

1.7 Summary of Substantial Equivalence Comparison to the Predicate Device

Both devices are distal attachments for endoscopes. The subject Pathfinder Endoscope Cap is comparable to the predicate in the following areas based on the following same technological and performance criteria:

- Constructed of soft, atraumatic material suitable for GI endoscopy
- Designed and labeled specifically for use with compatible endoscopes
- Tapering distal end design
- Sterile (EO)
- Single use
- Identical indications for use

While there are minor dimensional differences between the subject device and the predicate device, these differences are due to the need for compatibility with different manufacturers' endoscopes and for the subject device's compatibility with the Pathfinder Endoscope Overtube. These minor differences do not affect the safety and effectiveness of the Pathfinder Endoscope Cap in any way.

1.8 Performance Data: Summary of Functional and Performance Testing – Bench

The Pathfinder Endoscope Cap was subjected to the following mechanical testing.

- Dimensional and visual testing
- Cap tracking force (through compatible overtube)
- Cap tensile strength with tape

1.9 Performance Data: Summary of Biocompatibility Testing

The biocompatibility evaluation for the Pathfinder Endoscope Cap 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,'" September 2020, and ISO 10993-1, as recognized by the FDA and other applicable standards for laboratory practice and quality control. The battery of testing included:

- Cytotoxicity
- Sensitization
- Irritation
- Systemic Toxicity

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

1.10 Substantial Equivalence and Conclusion

The enclosed biocompatibility and performance testing results demonstrate that the subject device is safe and effective for its intended use and substantially equivalent to the predicate. Any superficial differences between the Pathfinder Endoscope Cap and the predicate cleared in K162749 are minor and do not raise questions of safety and effectiveness.