June 27, 2024

Neptune Medical, Inc.
℅ Keira Jessop
Regulatory Affairs Consultant
AlvaMed, Inc.
935 Great Plain Avenue, Unit 166
Needham, Massachusetts 02492

Re: K240853
Trade/Device Name: Pathfinder® CR System
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope And Accessories
Regulatory Class: Class II
Product Code: FED, FDS
Dated: May 24, 2024
Received: May 24, 2024

Dear Keira Jessop:

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. However, you are responsible to determine that the medical devices you use as components in the kit have either been determined as substantially equivalent under the premarket notification process (Section 510(k) of the act), or were legally on the market prior to May 28, 1976, the enactment date of the Medical Device Amendments. Please note: If you purchase your device components in bulk (i.e., unfinished) and further process (e.g., sterilize) you must submit a new 510(k) before including these components in your kit/tray. 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.

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,

Sivakami Venkatachalam -S

for
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: 07/31/2026
See PRA Statement below.

Submission Number *(if known)*

K240853

Device Name

Pathfinder® CR System

Indications for Use *(Describe)*

The Pathfinder® CR System is an accessory to the Pathfinder Endoscope Overtube, intended to be used with an endoscope to facilitate evacuation of retained blood, free-floating blood clots, and fluid from the stomach in adult patients (22 years of age or older).

It is for use only by medically licensed and trained gastroenterologists located in hospitals, clinics and doctors' offices.

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.

510(k) Summary

Name and Address of Submitter

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Submission Information

Subject Device:

Date Summary Prepared:	27 March 2024
Trade/Device Name:	Pathfinder® CR System
Manufacturer:	Neptune Medical, Inc.
Common Name:	Pathfinder® CR System
Regulation Number:	876.1500
Classification:	Class II
Primary Product Code:	FED, FDS
Review Panel:	Gastroenterology and Urology

Primary Predicate Device:

Trade/Device Name:	Pathfinder Endoscope Overtube (K211301)
Manufacturer:	Neptune Medical, Inc.
Common Name:	Endoscopic Access Overtube
Regulation Number:	876.1500
Classification:	Class II
Primary Product Code:	FED
Review Panel:	Gastroenterology and Urology

Secondary Predicate Device:

Trade/Device Name:	Pure-Vu EVS System (K232922)
Manufacturer:	Motus GI Medical Technologies Ltd.
Common Name:	Pure-Vu EVS System
Regulation Number:	876.1500
Regulation Class:	Class II
Product Code:	FDF, FDS
Review Panel:	Gastroenterology and Urology

Valid Predicate Discussion

Pathfinder Endoscope Overtube was selected as the valid primary predicate device and Pure-Vu EVS System was selected as the secondary predicate device to support the 510(k) submission because they received FDA clearance using well-established methods. Both the predicates meet the expected predicate performance due to no reports of unexpected injury, deaths, or malfunctions associated with the device. After conducting a search on the Manufacturer and User Facility Device Experience (MAUDE) Database, Medical Device Reporting (MDR), MedSun Reports Database, Medical Device Safety and CBER Safety & Availability (Biologics) and Recall Database websites, it was found that there are no known unmitigated use-related or design safety issues and both primary and secondary predicate devices have not been subject to a design-related recall.

Valid Predicate Device	**A - Well established methods**	**B - Meets or exceeds expected predicate performance**	**C - Unmitigated use-related or design-related safety issues**	**D – Associated design-related recall**
Pathfinder Endoscope Overtube (Primary Predicate)	Used relevant methods that were published in the public domain.	History of safe use established due to no reports of unexpected injury, deaths, or malfunctions associated with the device	No known unmitigated use related or design-related safety issues	No design-related recall identified
Pure-Vu EVS System (Secondary Predicate)	Used relevant methods that were published in the public domain.	History of safe use established due to no reports of unexpected injury, deaths, or malfunctions associated with the device	No known unmitigated use related or design-related safety issues	No design-related recall identified

Device Description

The Pathfinder® CR System is a disposable endoscopy fluid management system for the 14mm ID Pathfinder®Endoscope Overtube. It is designed to evacuate retained blood, free-floating blood clots, and fluid from the stomach in adult patients (22 years of age or older). It also provides access for endoscopic device passage and exchange. The suction adapter is attached to the Overtube and connected to a foot pedal to control suction on/off functionality. The foot pedal is connected to a suction source with vacuum regulator that provides a range between 200 to 375 mmHg (26.7 to 50.0 kPa). It is for use only by medically licensed and trained gastroenterologists located in hospitals, clinics, and doctor offices. The Pathfinder® CR System consists of the following main components:

Suction Adapter (CR, Adapter)
The suction adapter (CR) is a disposable adapter is attached to the Overtube to allow for passage of an endoscope composed of a rigid cap and body and two sealing components: a seal that interfaces with the Overtube handle grip and a scope seal that interacts with the endoscope. It has a side port for attachment to a suction source with a vacuum regulator such as a vacuum canister or wall vacuum.

Foot Pedal (Suction Controller)
The foot pedal (suction controller) is a spring-loaded pedal for engaging vacuum on and off. When depressed, the vacuum is engaged and the material from the patient is suctioned around the endoscope through the Overtube and CR, through the tubing and into a suction canister. When released, the vacuum is disengaged.

Suction Tubing (Tubing)
The suction tubing allows for removal of blood and fluid. It is connected to the CR side port, suction controller barbs and a suction source with vacuum regulator.

Indications for Use

The Pathfinder® CR System is an accessory to the Pathfinder Endoscope Overtube, intended to be used with an endoscope to facilitate evacuation of retained blood, free-floating blood clots, and fluid from the stomach in adult patients (22 years of age or older).
It is for use only by medically licensed and trained gastroenterologists located in hospitals, clinics, and doctors' offices.

Summary of Technological Characteristics

The following table provides an overview of general technological characteristics in comparison to both primary and secondary predicate devices. Any differences in the technological characteristics are minor and reflect market strategy and/or perceived user preferences and do not impact the safety, effectiveness, or substantial equivalence of the device. Biocompatibility evaluation testing, and performance testing have been performed on the subject device in order to establish substantial equivalence to the predicate devices.

Table 1: Summary of Technological Characteristics

	Subject Device	**Primary Predicate**	**Secondary Predicate**
Manufacturer	Neptune Medical, Inc.	Neptune Medical, Inc.	Motus GI Medical Technologies Ltd.
Trade Name	Pathfinder CR System	Pathfinder Endoscope Overtube	Pure-Vu EVS System
K#	TBD	K211301	K232922
Device Classification Name	Endoscopic access overtube, gastroenterology-urology	Endoscopic access overtube, gastroenterology-urology	Colonoscope and accessories, flexible/rigid
Classification	Regulation No: 876.1500 Class: II Panel: Gastroenterology and Urology	Regulation No: 876.1500 Class: II Panel: Gastroenterology and Urology	Regulation No: 876.1500 Class: II Panel: Gastroenterology and Urology
Product Code	FED, FDS	FED	FDF, FDS
Indications for Use	The disposable Pathfinder® CR System is an accessory to the Pathfinder Endoscope Overtube, intended to be used with an endoscope to facilitate evacuation of retained blood, free-floating blood clots, and fluid from the stomach in adult patients (22 years of age or 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 Pure-Vu EVS System is intended to connect to standard or slim colonoscopes and gastroscopes to help facilitate intra-procedural cleansing of the GI tract by irrigating or cleaning and evacuating irrigation fluid (water), feces, and other bodily fluids and matter, e.g. blood.

	It is for use only by medically licensed and trained gastroenterologists located in hospitals, clinics, and doctors' offices.		It is for use only by trained medical personnel located in hospitals, clinics and doctors' offices.
Environment of Use	Hospitals, clinics, and/or doctor's offices	Hospitals, clinics, and/or doctor's offices	Hospitals, clinics, and/or doctor's offices
Prescriptive	Yes	Yes	Yes
Technological Characteristics			
Disposable	Yes	Yes	Yes, except for workstation
Principle of Operation	Proximal attachment to Pathfinder Overtube with insertion of endoscope through both Pathfinder CR System and Pathfinder Overtube. Suction at any time during procedure. Debris and fluids are removed through the suction channel into an external waster container.	Insertion of endoscope through Pathfinder Overtube. Vacuum-assisted rigidizing overtube for endoscopic procedures in the GI Tract.	Distal Attachment to the endoscope. Vacuum Suction at any time during the procedure without removing any tools. Debris and fluids are removed through the suction channel into an external waster container
Maximum Suction Pressure Specifications	(-)0.5 Bar / (375mmHg)	N/A - Closed system	(-)0.5 Bar / (375mmHg)
Sterilization of Patient Contacting Components	Sterile	Sterile	Clean, Non-Sterile
Material	Complies with ISO 10993	Complies with ISO 10993	Complies with ISO 10993
Electrical Input	N/A	N/A	100V-240V/50/60 HZ

Summary of Biocompatibility Testing:

The Suction Adapter is the only component of the system that is considered to have any indirect or direct contact with the patient.

Biocompatibility testing of the Suction Adapter materials included:

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

Testing demonstrated that the material used in the Suction Adapter meets the requirements of the applicable ISO 10993 standard.

Summary of Non-Clinical Functional and Performance Testing

The Pathfinder® CR system was subject to extensive testing under applicable design control requirements, including:

- Dimensional Measurements
- Adapter Scope Installation
- Endoscope Trackability
- Device Trackability
- System Flow Rate
- Adapter Tubing Installation and Removal
- Adapter Tensile Integrity
- Adapter Cantilever Integrity
- Adapter Scope and Cantilever Seal
- Adapter Torque
- Foot Pedal Cyclic and Actuation Force
- Foot Pedal Tubing Installation and Removal
- Simulated Use

Together, these verification/validation activities successfully demonstrated that the device

correctly performs as designed, has been validated for its intended use, and raises no new questions regarding either safety or effectiveness when compared to the predicate device. Therefore, the verification/validation testing conducted supports a determination of substantial equivalence for the subject device.

Summary of Clinical Data

No clinical testing was applicable to this submission.

Summary of Animal Data

No animal testing was applicable to this submission.

Shelf Life and Sterilization

Neptune Medical is responsible for the sterilization of the Suction Adapter component of the Pathfinder® CR system. The Suction tubing is purchased sterile, so Neptune Medical is not responsible for its sterilization process. The foot pedal is provided non-sterile; therefore, sterility validation is not applicable
Ethylene Oxide (EO) is used as the method of Sterilization and the proposed shelf life of the device is 6 months from the date of manufacture.

Conclusion

Neptune Medical considers the Pathfinder CR System to be substantially equivalent to the primary and secondary predicate. Like the primary predicate, Pathfinder Endoscope Overtube, and the secondary predicate, Pure-Vu EVS System, the Pathfinder® CR System has been shown to be safe and effective through bench testing and biocompatibility testing. Differences in design and technology do not raise any unanswered questions of safety or effectiveness and the intended use remains unchanged.

The information present in the 510(k) supports that the Pathfinder® CR System is as safe, as effective, and performs as well as the predicate devices and substantially equivalent to the identified primary and secondary predicate devices in design rationale, methodology of use, and performance.

In accordance with the Federal Food, Drug and Cosmetic Act, 21 CFR Part 807 and based on the information provided in this premarket notification it can be concluded that the subject device is substantially equivalent with predicate devices.