January 14, 2025

PFM Medical, Inc.
Madison Reid
Regulatory Affairs Coordinator
1916 Palomar Oaks Way, Suite 150
Carlsbad, CA 92008

Re: K241278
Trade/Device Name: ASEPT® Glide Peritoneal Drainage System
Regulation Number: 21 CFR§ 876.5630
Regulation Name: Peritoneal Dialysis System and Accessories
Regulatory Class: II
Product Code: PNG
Dated: December 13, 2024
Received: December 13, 2024

Dear Madison Reid:

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. 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.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

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,

Maura Rooney -S

Maura Rooney
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)*

K241278

Device Name

ASEPT® Glide Peritoneal Drainage System

Indications for Use *(Describe)*

The ASEPT Glide Peritoneal Drainage System is indicated for intermittent, long-term drainage of symptomatic, recurrent, malignant and non-malignant ascites that does not respond to medical management of the underlying disease and for the palliation of symptoms related to recurrent ascites.
The use of the ASEPT Glide Peritoneal Catheter for non-malignant ascites is limited to patients who are intolerant or resistant to maximum medical therapy, refractory to large volume paracentesis (LVP) and are not candidates for trans-jugular intrahepatic portosystemic shunt or LVP. The ASEPT Glide Peritoneal Catheter is indicated for adults only.

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.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

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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."

This 510(k) summary of safety and effectiveness is being submitted in accordance with the requirements of 21 CFR 807.92.

I. SUBMITTER

PFM Medical, Inc
1916 Palomar Oaks Way, Suite 150
Carlsbad, CA 92008, USA

Contact Person: Madison Reid
Regulatory Affairs Coordinator
PFM Medical, Inc
mreid@pfmmedicalusa.com

Date Summary Prepared: January 9, 2024

II. DEVICE

Trade or Proprietary Name	ASEPT® Glide Peritoneal Drainage System
Regulation Name	Peritoneal dialysis system and accessories
Device Class	Class II
Regulation Number	21 CFR §876.5630
FDA Product Code	PNG, Peritoneal, Drainage Catheter for Refractory Ascites, Long-Term Indwelling

III. LEGALLY MARGETED PREDICATE DEVICES

Predicate Device		
510(k)	**Product Name**	**Clearance Date**
K221779	ASEPT Peritoneal Drainage System	May 02, 2023

IV. DEVICE DESCRIPTION

The ASEPT Glide Peritoneal Drainage System provides patients with a method to drain accumulated fluid from the abdomen. The primary components of the system are the indwelling ASEPT Glide Peritoneal Catheter and the ASEPT Drainage Kit. The catheter is placed in the patient's peritoneal cavity enabling the patient to perform periodic peritoneal drainage at home or in the hospital. The device is provided sterile.

The ASEPT Glide Peritoneal Drainage Catheter has a surface modification applied from the distal tip to the polyester cuff.

V. INTENDED USE

The intended use of an indwelling peritoneal drainage catheter is for drainage of refractory ascites with long-term occurrence from the peritoneal cavity.

VI. INDICATIONS FOR USE

The ASEPT Peritoneal Drainage System is indicated for intermittent, long-term drainage of symptomatic, recurrent, malignant, and non-malignant ascites that does not respond to medical management of the underlying disease and for the palliation of symptoms related to recurrent ascites.

The use of the ASEPT Glide Peritoneal Catheter for non-malignant ascites is limited to patients who are intolerant or resistant to maximum medical therapy, refractory to large volume paracentesis (LVP) and are not candidates for a trans-jugular intrahepatic portosystemic shunt or LVP. The ASEPT Glide Peritoneal Catheter is indicated for adults only.

VII. TECHNICAL COMPARISON TO PREDICATE

The technological design features of the subject device including intended use, design, materials, drainage function and method, and fundamental scientific technology were qualified and compared to the predicate device and it was demonstrated that they are substantially equivalent.

VIII. PERFORMANCE DATA

Bench testing was performed on the ASEPT Glide Peritoneal Catheter and replacement valve to demonstrate substantial equivalence. The performance testing requirements were determined by the predicate and reference devices and assessment of risk. Biocompatibility was tested in accordance with ISO 10993 standards. The device sterilization process was validated in accordance with ISO 11135:2014.

IX. SUMMARY OF CLINICAL TESTS REFERENCED

No clinical tests were required to confirm the safety and effectiveness of the subject device.

X. CONCLUSION

Based on the information provided in this 510(k) submission, it has been determined that the subject device is as safe, as effective and performs as well or better than the legally marketed predicate device.