May 2, 2023

PFM Medical, Inc.
Jessica Jho
Director of Regulatory Affairs
1916 Palomar Oaks Way, Suite 150
Carlsbad, California 92008

Re: K221779
Trade/Device Name: ASEPT® Peritoneal Drainage System
Regulation Number: 21 CFR 876.5630
Regulation Name: Peritoneal dialysis system and accessories
Regulatory Class: Class II
Product Code: PNG
Dated: March 30, 2023
Received: March 31, 2023

Dear Jessica Jho:

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. However, you are responsible to determine that the medical devices you use as components in the kits 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 kits. 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,

Gema Gonzalez -S

Gema Gonzalez, MS
Acting 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)*
K221779

Device Name
ASEPT® Peritoneal Drainage System

Indications for Use *(Describe)*

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 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 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:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"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."

pfmmedical

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:
Jessica Jho
Director, Regulatory Affairs
PFM Medical, Inc
JJho@pfmmedicalusa.com

Date Summary Prepared: May 1, 2023

II. DEVICE

Trade or Proprietary Name: ASEPT® Peritoneal Drainage System
Common Name: Peritoneal catheter, long term, indwelling

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**
K093796	ASEPT Peritoneal Drainage System	February 26, 2010
Reference Device		
510(k)	**Product Name**	**Clearance Date**
K201155	PleurX Peritoneal Catheter System	October 21, 2020

pfmmedical

IV. DEVICE DESCRIPTION

The ASEPT 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 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.

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 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 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 compared to the predicate device and it was demonstrated that they are substantially equivalent.

VIII. PERFORMANCE DATA

Bench testing was performed on the ASEPT 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.

pfmmedical

IX. SUMMARY OF CLINICAL TESTS REFERENCED

No clinical tests were conducted for this submission. The modified indications for use statement was supported using a clinical literature review. The literature review demonstrates that peritoneal drainage catheters have a history of safety and efficacy in non-malignant refractory ascites and that the incidence of device related complications is more closely related to patient specific health status and preferences than the underlying cause (malignant vs non-malignant) of ascites.

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.