

K093796
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510(k) Summary of Safety and Effectiveness

The following section is included as required by the Safe Medical Device Act (SMDA) of 1990.

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Oceanside, CA 92056
CONTACT PERSON: SALVADORE F. PALOMARES, RAC

FEB 26 2010

510(k) Summary of Safety and Effectiveness

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

The assigned 510(k) number is:

Trade Name: Asept Peritoneal Drainage System
Common Name: Catheter, Peritoneal, Long-Term Indwelling and Accessories
Classification: FJS

Equivalent Devices:

Manufacturer: Denver Biomedical (Cardinal Health)
Name: Pleurx Peritoneal Catheter Kit and Pleurx Drainage Kits
510(k) #: K051711

Manufacturer: PFM Medical
Name: Asept Pleural Drainage System
510(k) #: K093307

Device Description:

The Asept Peritoneal Drainage System is a tunneled, indwelling catheter used to drain accumulated fluid from the abdomen. The catheter is implanted in the patient's peritoneal cavity enabling the patient to perform periodic peritoneal drainage at home or hospital. The primary components of the system are the Asept indwelling Peritoneal Catheter and the Asept Drainage Kit. The proximal end of the indwelling catheter has a valve that prevents fluid or air from moving in or out of the peritoneal space until the valve is breached. The valve can be breached by the Asept Peritoneal Drainage catheter connected to wall suction or pleurovac or vacuum bottles. The Asept Peritoneal Drainage System provides patients with a convenient way to relieve malignant ascites symptoms at home.

Intended Use:

The Asept Peritoneal Drainage System is indicated for periodic drainage of recurrent and symptomatic malignant ascites. The catheter is intended for long term access of the peritoneal cavity in order to relieve symptoms such as dyspnea.

Performance Data:

In vitro testing was performed on the Asept Peritoneal Drainage System to assure reliable design and performance in accordance with BS EN 1618-1997. Testing includes leakage, flow rate, tensile strength, and corrosion.

Clinical studies were not deemed necessary since in vitro testing was sufficient to demonstrate safety and effectiveness by way of comparison to legally marketed predicate device.

Biocompatibility:

Materials used in the Asept Peritoneal Drainage System meet the requirements of ISO 10993 or identical to legally marketed devices.



Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room W-066-0609
Silver Spring, MD 20993-0002

Salvadore F. Palomares, RAC
Director of Regulatory Affairs
PFM Medical, Inc.
2605 Temple Heights Drive, Ste. A
OCEANSIDE CA 92056

FEB 26 2010

Re: K093796

Trade/Device Name: Asept Peritoneal Drainage System
Regulation Number: 21 CFR §876.5630
Regulation Name: Peritoneal dialysis system and accessories
Regulatory Class: II
Product Code: FJS
Dated: December 10, 2010
Received: December 11, 2010

Dear Mr. Palomares:

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). You may, therefore, market the device, subject to the general controls provisions of Act. 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 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. 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.

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); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

In addition, we have determined that your device kit contains Lidocaine HCl, 1%, and Povidone iodine swabs, which are subject to regulation as drugs.

Our substantially equivalent determination does not apply to the drug components of your device. We recommend you first contact the Center for Drug Evaluation and Research before marketing your device with the drug components. For information on applicable Agency requirements for marketing this [these] drug[s], we suggest you contact:

Director, Division of Drug Labeling Compliance
Center for Drug Evaluation and Research
Food and Drug Administration
5600 Fishers Lane
Rockville, Maryland 20857
(301) 594-0101

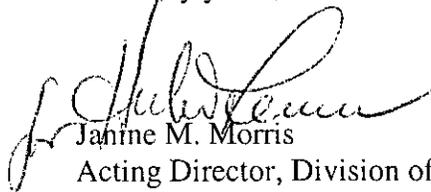
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to <http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm> for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

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You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address <http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,



Janine M. Morris
Acting Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

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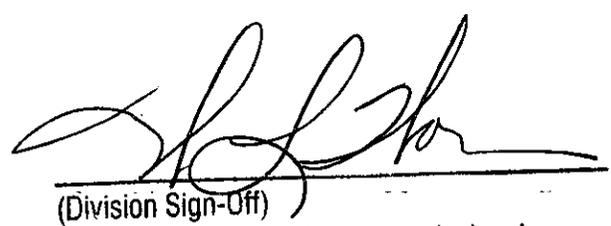
Device Name: Asept Peritoneal Drainage System

Indications for Use: The Asept Peritoneal Drainage System is indicated for periodic drainage of recurrent and symptomatic malignant ascites. The catheter is intended for long term access of the peritoneal cavity in order to relieve symptoms such as dyspnea.

Prescription Use X AND/OR Over the Counter Use _____
(Per 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)



(Division Sign-Off)
Division of Reproductive, Abdominal and
Radiological Devices
510(k) Number K093796