510(k) Summary of Safety and Effectiveness

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

Name: PFM Medical, Inc
Address: 2605 Temple Heights Drive
Oceanside, CA 92056
CONTACT PERSON: SALVADORE F. PALOMARES, RAC

DEC 1 2 2007

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: T-Port HP Infusion Port
Common Name: Port & Catheter Implanted, Subcutaneous, Intravascular
Classification Name: Same

Equivalent Devices:
Manufacturer: PFM Medical, Inc
Name: T-Port HP Infusion Port
510(k) #: K071993

Device Description:

The T-Port HP Infusion Port is an implantable device designed to provide repeated access to the vascular system without the trauma associated with multiple vena puncture. The system consists of a self-sealing injection port and a delivery catheter for the receipt and delivery of medications to the selected body site. The T-Port HP Infusion Port is offered with the polyurethane catheter either pre-attached by the manufacturer or attachable for application by the inserting physician. The port can be anchored with sutures in the port pocket for secure seating. The catheter lock provides securement of the catheter to the port. Introduction of solution into the implanted port and catheter system is through a non-coring needle.

The base of the port has the letters "CT" to signify that it can be used for power injection on contrast agents. The serial number is laser etched into the base of the port. The suture holes may contain clear silicone to prevent tissue in growth to the suture holes.

Power injection of contrast media, can be safely administered with a 19 or 20 gauge power injectable infusion non-corning needle at a maximum recommended infusion rate of 5 ml/sec or a 22 gauge power injectable non-coring needle at a maximum recommended infusion rate of 2 ml/sec. Maximum pressure should not exceed 300 psi.

The T-Port HP Infusion Port is packaged with the necessary accessories to facilitate catheter insertion.

The port and catheter are manufactured and sterilized at the same manufacturing and sterilization facilities as the predicate device cleared under K071993. .

Components will be assembled into standard configurations or configurations specified by the customer and packaged.

The device includes the following components:

- Implantable Port
- Click Connector
- Guide Wire
- Dilator
- Tunneling Needle
- Vein Lifter
- Nurses Guide
- Companion Checklist
- Catheter
- Huber Needle
- Introducing Needle
- Peel Away Sheath
- Syringe
- Instructions for Use
- Patient Guide
- Patient ID Card & Key Ring Card

Intended Use:
The T-Port HP Infusion Port is indicated for patient therapies requiring repeated access to the vascular system. The port system can be used for infusion of medications, IV fluids, parenteral nutrition solutions, blood products and for the withdrawal of blood samples.

When used with a power injectable needle, the T-Port HP Infusion Port is indicated for power injection of contrast media. For power injection of contrast media, the maximum recommended infusion rate is 5 ml/sec with a 19G or 20G non-coring power injectable needle or 2 ml/sec with a 22G non-coring power injectable needle.

Biocompatibility:
The materials used to manufacture the T-Port HP Infusion Port are used in legally marketed devices under comparable conditions of use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC 1 2 2007

Mr. Salvadore F. Palomares, RAC
Director of Regulatory Affairs
PFM Medical, Incorporated
2605 Temple Heights Drive, Suite A
Oceanside, California 92056

Re: K073210
Trade/Device Name: T-Port HP Infusion Port
Regulation Number: 21 CFR 880.5965
Regulation Name: Subcutaneous, Implanted, Intravascular Infusion Port and Catheter
Regulatory Class: II
Product Code: LJT
Dated: November 12, 2007
Received: November 16, 2007

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 (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. 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 such 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); 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.

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 contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). 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 (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Chiu Lin, Ph.D.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K073210

510(k):

Device Name: **T-Port HP Infusion Port**

Indications for Use: The T-Port HP Infusion Port is indicated for patient therapies requiring repeated access to the vascular system. The port system can be used for infusion of medications, IV fluids, parenteral nutrition solutions, blood products and for the withdrawal of blood samples.

When used with a power injectable needle, the T-Port HP Infusion Port is indicated for power injection of contrast media. For power injection of contrast media, the maximum recommended infusion rate is 5 ml/sec with a 19G or 20G non-coring power injectable needle or 2 ml/sec with a 22G non-coring power injectable needle.

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use X Or _____ Over the Counter Use
(Per 21 CFR 801.109)

Anthony D. Watson
(Division Sign-Off)

Division of Dental, Infection Control, and
General Hospital Devices

510(k) Number K073210