K083873

MAR 19 2009

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

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: PICC (CT Rated and Non-Rated)
Common Name: Catheter, Intravascular, Therapeutic, Long Term
Classification: LJS

Equivalent Devices:
Manufacturer: PFM Medical
Name: PFM PICC
510(k) #: K072391

Manufacturer: HDC Corporation
Name: V-Cath Power PICC
510(k) #: K071875

Device Description:
The PICC (CT Rated and Non-Rated) is a family of peripherally inserted central venous catheters designed to perform infusion, intravenous therapy, and blood sampling. The catheters, made of radiopaque polyurethane tubing, are inserted peripherally. Each PICC has a kink resistant, reverse tapered catheter design. The PICC kit includes a catheter and introduction components. The catheter is supplied sterile and non-pyrogenic in a variety of kit configurations.

The PICC (CT Rated and Non-Rated) is indicated for dwell times shorter or greater than 30 days.

The PICC (CT Rated and Non-Rated) product line has catheters in 4 Fr and 5 Fr single lumen and 5 Fr and 6 Fr dual lumen. The catheters are attached to an injection-molded polyurethane hub that has extension legs with Luer lock fittings for access attachment.

The CT rated PICC is also indicated for the power injection of contrast media studies. The CT rated PICC catheter assemblies have been tested to withstand power injection of worst-case viscosity injection media at 5 ml/sec with a maximum power injector pressure of 300 psi. All PICC products have a maximum recommended infusion rating of 5 ml/sec. The maximum pressure or pounds per square inch (psi) of the power injector utilized should not exceed 300 psi.

Intended Use:
The PICC (CT Rated and Non-Rated) is indicated for short or long term peripheral access to the central venous system for infusion, intravenous therapy, and blood sampling.

The CT rated PICC is also indicated for the power injection of contrast media.
The CT rated PICC has a maximum recommended infusion rating of 5 ml/sec.
The maximum pressure or pounds per square inch (psi) of the power injector utilized should not exceed 300 psi.

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Performance Data:
In vitro testing was performed on the PICC (CT Rated and Non-Rated) to assure reliable design and performance in accordance with established standards and specifications. Testing includes tensile strength, dynamic flow, dynamic failure, static burst, power injection performance and life cycle power injection.

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:
Biocompatibility testing on the PICC (CT Rated and Non-Rated) demonstrates that the materials used meet the requirements of ISO 10993 for a permanent contact device.

CONCLUSION
The PICC (CT Rated and Non-Rated) met all established acceptance criteria for performance testing and design verification testing. This testing demonstrated that the PICC (CT Rated and Non-Rated) is safe and effective for its intended use, and is substantially equivalent to the following predicate devices: V-Cath Power PICC (HDC Corp, SE-K071875) and PFM PICC (PFM Medical, SE-072391)

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 19 2009

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

Re: K083873
Trade/Device Name: PICC (CT Rated and Non-Rated)
Regulation Number: 21 CFR 880.5970
Regulation Name: Percutaneous, Implanted, Long-term Intravascular Catheter
Regulatory Class: II
Product Code: LJS
Dated: December 23, 2008
Received: December 29, 2008

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 Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. 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/cdrh/industry/support/index.html.

Sincerely yours,

for Ginette Y. Michaud, M.D.
Acting Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

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510(k):

Device Name: **PICC (CT Rated and Non-Rated)**

Indications for Use: The PICC (CT Rated and Non-Rated) is indicated for short or long term peripheral access to the central venous system for infusion, intravenous therapy, and blood sampling.

The CT rated PICC is also indicated for the power injection of contrast media.
The CT rated PICC has a maximum recommended infusion rating of 5 ml/sec.
The maximum pressure or pounds per square inch (psi) of the power injector utilized should not exceed 300 psi.

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 Anesthesiology, General Hospital
Infection Control, Dental Devices

510(k) Number: K083873