K040533

SEP 17 2004

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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.

Name: pfm Medical, Inc
Address: 2620 Temple Heights Drive
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: EZ Huber Safety Infusion Set
Common Name: Intravascular Administration Set
Classification Name: Same

Equivalent Devices:
Manufacturer: pfm Medical, Inc
Name: Jetcan Huber Needle Set
510(k) #: K002471

Device Description:

The EZ Huber Safety Infusion Set is a single use, sterile and non-pyrogenic device intended for use as an accessory to deliver solutions and drugs into a patient's vascular implant port. The EZ Huber Safety Infusion Set incorporates an active safety feature that aids in the prevention of accidental needle sticks. When removing the EZ Huber Safety Infusion Set, the healthcare provider stabilizes the port by placing two fingers on the small wings of the EZ Huber Safety Infusion Set. The cannula is withdrawn by pulling on the large wings. As the cannula is withdrawn, the Huber needle housing (with small wings) slide over the cannula and lock over the cannula tip, rendering the cannula from being reused and preventing accidental needle sticks. A plastic shroud surrounds the cannula shaft between the large wings and the small wings/cannula tip. The shroud prevents exposure to any biohazardous materials on the cannula shaft.

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

Types of components that may be contained in a set include:

- Huber Needle Housing
- Huber Needle Wing
- Tubing
- Clamps
- Y-Site Injection Ports
- Stopcock

Intended Use:
The EZ Huber Safety Infusion Set is a device used to administer fluids from a container to a patient's vascular system through an implanted port. The EZ Huber Safety Infusion Set incorporates an active safety feature that aids in the prevention of accidental needle sticks.

Biocompatibility:
The materials used to manufacture the EZ Huber Safety Infusion Set 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

SEP 17 2004

Mr. Salvadore F. Palomares
Regulatory Affairs Consultant
PFM Medical, Incorporated
2620 Temple Heights Drive
Oceanside, California 92056

Re: K040533
Trade/Device Name: EZ Huber Safety Infusion Set
Regulation Number: 880.5440
Regulation Name: Intravascular Administration Set
Regulatory Class: II
Product Code: FPA
Dated: September 2, 2004
Received: September 3, 2004

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.

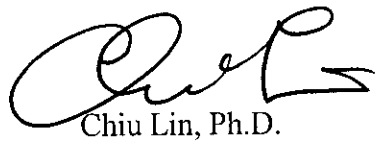
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish 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 (301) 594-4618. 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/dsma/dsmamain.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

K040533

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Pfm Medical, Inc **EZ Huber Safety Infusion Set**

Indications for Use

510(k) Number: K040533

Device Name: **EZ Huber Safety Infusion Set**

Indications for Use: The EZ Huber Safety Infusion Set is a device used to administer fluids from a container to a patient's vascular system through an implanted port. The EZ Huber Safety Infusion Set incorporates an active safety feature that aids in the prevention of accidental needle sticks.

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)

William M. Burdick Jr
Anthony D. Watson 9/16/04

(Division Sign-Off)
Division of Anesthesiology, General Hospital,
Infection Control, Dental Devices

510(k) Number: K040533