K090300

APR 30 2009

510(k) SUMMARY

Ace Medical Autofuser Elastomeric Infusion Pump System

Submitted by:

Ace Medical US, LLC

9102 Turfway Bend Drive, Powell, OH 43065-8497

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Establishment Registration: 3005627389

Date Prepared: January 31, 2009

Device Information:

Name of Device: Autofuser Elastomeric Infusion Pump System

Common Name: Elastomeric Infusion Pump & Procedure Kit

Classification Name: Elastomeric Infusion Pump

Product code: MEB – Elastomeric Infusion Pump

Device Classification: Class II

Regulation Number: 880.5725

Classification Panel: 80, General Hospital and Personal Use Device

Predicate Device

Ace Medical Autofuser Elastomeric Infusion Pump System (K060258)

Intended Use / Indications for Use

The Autofuser family of ambulatory infusion pumps with integrated administration set, either separately or as part of a convenience kit, is intended for general infusion use. Routes of administration include intravenous, percutaneous, subcutaneous, intra-arterial and epidural, and into intra-operative (soft tissue/body cavity) sites. Within the Autofuser family are pump models intended for patient-controlled infusion using the integrated bolus button. General infusion uses include continuous infusion of a local anesthetic near a nerve for regional anesthesia and pain management for pre-operative, perioperative and postoperative surgery.

Technological Characteristics

The Autofuser system consists of a family of disposable infusion pumps and associated procedure kits. The pump is comprised of a balloon-style medication reservoir and an integrated flowrate-controlling administration set. When the Autofuser pump is packaged in a procedure kit, the kit includes legally marketed components such as filling syringe, catheter, catheter introducer, and pump carrying pouch.

Performance Data

Performance testing was performed to verify/validate the modifications to the system. Test results demonstrate that the modified Autofuser system met its predetermined performance specifications.

Substantial Equivalence

The modified Autofuser system is as safe and effective as the previously-cleared Autofuser system. The modified device has the same intended uses and similar indications, technological characteristics, and principles of operation as its predicate device. The minor technological differences between the modified device and its predicate device raise no new issues of safety or effectiveness. Performance data demonstrate that the modified Autofuser is as safe and effective as the predicate device. Thus, the modified Autofuser system is substantially equivalent to the previously-cleared predicate Autofuser system.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

APR 30 2009

Mr. Andrew N. Lamborne
Ace Medical US, LLC
9102 Turfway Bend Drive
Powell, Ohio 43065

Re: K090300
Trade/Device Name: Autofuser Elastomeric Infusion Pump System
Regulation Number: 21 CFR 880.5725
Regulation Name: Infusion Pump
Regulatory Class: II
Product Code: MEB
Dated: March 24, 2009
Received: March 31, 2009

Dear Mr. Lamborne:

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 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.

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 the reporting of adverse events under the MDR regulation (21 CFR Part 803), please contact the CDRH/Office of Surveillance and Biometrics/Division of Postmarket Surveillance at 240-276-3464. For more information regarding the reporting of adverse events, please go to http://www.fda.gov/cdrh/mdr/.

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,

Susan Runner, D.D.S., MA
Acting Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use Statement

510(k) Number (if known): K090300

Device Name: Autofuser Elastomeric Infusion Pump System

Indications for Use:

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Prescription Use ___X___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

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

510(k) Number: K090300