K060258

MAY 30 2006

510(k) Summary

Modifications to the Ace Medical Autofuser System

19 January 2006

Submitted by: Ace Medical US, LLC, 9102 Turfway Bend Drive, Powell, OH 43065-8497
Contact for Questions: Andy Lamborne, 303-443-7500 x.228, alamborne.co@netzero.net
Trade Name: Autofuser
Common Name: Elastomeric Infusion Pump & Procedure Kit
Classification Name: Elastomeric Infusion Pump
Device Classification: Class II
Regulation Number: 880.5725
Classification Panel: 80, General Hospital and Personal Use Device
Product code: MEB – Elastomeric Infusion Pump
Original cleared 510(k): K041585
Establishment Registration: pending assignment from FDA
Owner/Operator Number: 9082449

5. Summary of Safety and Effectiveness of the Autofuser System

5.1 This premarket notification submission is intended to notify the Food and Drug Administration that Ace Medical US, LLC intends to market a modification to an existing device (K041585), the Autofuser system.

5.2 The cleared indications for use for the Autofuser system are:

> 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.

5.3 Summary of the Modification

5.3.1 The modification to the existing device is the addition of new flow rates, new reservoir size and procedure kit components.

5.3.2 A risk analysis for the modified Autofuser device has been performed, incorporating risk analysis, risk evaluation and risk control in accordance with ISO 14971.

a. The risk control measures are verified and/or validated, as appropriate.

b. The design verification and validation activities have been performed and the results demonstrate that the predetermined acceptance criteria were met. These results demonstrate that the modified device is substantially equivalent to the cleared original device.

5.3.3 The kit components are legally marketed—either pre-amendment devices, devices exempt from premarket notification, or devices found to be substantially equivalent through the premarket notification process for the intended use of the kit. The kit components are substantially equivalent to the components included in pain management kits for the original Autofuser, the Accufuser and the OnQ/Painbuster predicate devices.

5.4 Conclusion: The modified Autofuser system does not raise any new safety and efficacy concerns when compared to the original Autofuser device that is already legally marketed. The modified Autofuser system is substantially equivalent to the original cleared Autofuser (K041585). The modified Autofuser system also demonstrates substantial equivalence to the Woo Young/McKinley Medical Accufuser System (K033039), and to the I-Flow Homepump/Eclipse/OnQ Painbuster system (K980558, K982946, K944692, K896546).

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 30 2006

Mr. Andrew N. Lamborne
Technical Advisor
Ace Medical US, LLC
9102 Turfway Bend Drive
Powell, Ohio 43065-8497

Re: K060258
Trade/Device Name: Autofuser
Regulation Number: 880.5725
Regulation Name: Infusion Pump
Regulatory Class: II
Product Code: MEB
Dated: March 20, 2006
Received: March 28, 2006

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 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) 276-0115. 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

K 060258

Indications for Use

510(k) Number (if known): K060258

Device Name: Autofuser

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.

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

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Anthony D. Watson

[illegible] Cardiology, General Hospital,
[illegible] Control, Dental Devices

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