

AUG 26 2004

K041585

SUMMARY OF SAFETY AND EFFECTIVENESS

June 1, 2004

Trade Name: AutoFuser Elastomeric Infusion Pump

Common Name: Elastomeric Infusion Pump

Classification Name: Pump, Infusion, Elastomeric

Classification Panel: General Hospital and Personal Use Device

All questions and/or comments concerning this document should be made to:

Robert J. Bard, Esq.
Managing Director

HealthCare Technologies Consultants
150 Lake Village Dr
Suite 203
Telephone: 949.235.0545
Fax: 949.240.3460

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1.0 DESCRIPTION OF THE AUTOFUSER PRODUCT

- 1.1 The AutoFuser pump (Continuous type Silicone Balloon)
 - 1.1.1 The pump provides continuous fluid delivery with attached, fixed rate administration set.
 - 1.1.2 The pumps are supplied as fixed flow rates.
 - 1.1.3 A silicone balloon is used as both the fluid reservoir of the device and the pressure (energy) source.
- 1.2 The AutoFuser pump family includes models of the standard AutoFuser with the addition of a Patient Medication Control Module (PCM)
 - 1.2.1 Patient Medication Control Module allows the patient to administer a bolus of fixed volume with a fixed lockout (re-fill) time.
 - 1.2.2 The pump is a disposable device intended for single patient use.
 - 1.2.3 The pump is suitable for use as an ambulatory device and is intended for use in the hospital, home environment or alternative care sites.
 - 1.2.4 The AutoFuser and the AutoFuser PCM pumps are substantially similar to the I-Flow Homepump (Eclipse) C-Series (included in the I-Flow PainBuster kit and the On-Q pain management kit), the Baxter Infuser and Intermate, the McKinley Accufuser, and the B Braun spring pump (used in the Sgarlato pain kit).

2.0 THE AUTOFUSER/AUTOFUSER PCM PUMP AND ITS PREDICATE DEVICES ARE INTENDED:

- 2.1 For general infusion use. Routes of infusion include intravenous, percutaneous, subcutaneous, intra-arterial and epidural and into the intra-operative (soft tissue / body cavity) site.
- 2.2 General infusion use Includes pain management for pre-operative, perioperative and postoperative surgery.
 - 2.2.1 The predicate pumps (and the pumps included with the I-Flow PainBuster and ON-Q Infusion Kit and the Sgarlato Pain Control Infusion Pump (PCIP)) have the same intended use as the device under review:

2.2.2 The AutoFuser family of ambulatory infusion pumps with integrated administration set, either separately or as part of a convenience kit, and its predicate devices are indicated for general infusion use. Routes of infusion include intravenous, percutaneous, subcutaneous, inter-arterial and epidural, and into intra-operative (soft tissue / body cavity) sites.

Members of the AutoFuser family and the predicate devices are also 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.

2.3 Device Descriptions

2.3.1 Specifications

2.3.1.1 The AutoFuser and the AutoFuser PCM pumps have fill volumes and flow rates substantially similar to the pumps of the McKinley Medical Accufuser, the I-Flow PainBuster (Homepump Eclipse C-Series), the B Braun spring pump included in the Sgarlato PCIP, and the Baxter Infusor and Intermate pumps.

2.3.2 Flow Control

2.3.2.1 The AutoFuser and AutoFuser PCM pumps and the identified predicate device use either a glass orifice or PVC tubing to control the flow rate.

2.3.3 Materials

2.3.3.1 All fluid path materials of the AutoFuser pumps are in conformance with ISO 10993 Part 1.



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 26 2004

ALGOS, LC
C/O Mr. Robert J. Bard
Managing Director
Healthcare Technologies Consultants
150 Lake Village Drive, Suite 203
Ann Arbor, Michigan 48103

Re: K041585
Trade/Device Name: AutoFuser Infusion Pump
Regulation Number: 880.5725
Regulation Name: Infusion Pump
Regulatory Class: II
Product Code: MEB
Dated: June 1, 2004
Received: June 14, 2004

Dear Mr. Bard:

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.

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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

Indications for Use

510(k) Number (if known): K041585

Device Name: AutoFuser infusion pump

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 infusion include intravenous, percutaneous, subcutaneous, inter-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.

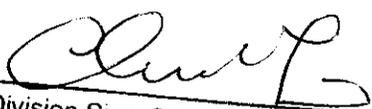
Prescription Use
 (Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use _____
 (21 CFR 801 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)



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

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