McKinley

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APR 14 2005 K050770

510(k) Summary

Traditional 510(k) for Modifications to the McKinley Accufuser, Accufuser Plus, and Standard Procedure Kit

Date Prepared:	March 23, 2005
Submitted by & 510(k) Owner:	McKinley Medical, LLC 4080 Youngfield Street Wheat Ridge, CO 80033 303-420-9569 Fax: 720-258-0127
Contact for questions:	Ralph Cooey 303-420-9569 x204 Fax: 720-258-0127 rcooey@mckinleymed.com
Establishment Registration:	1723533
Owner/Operator Number:	9027257
Trade Name:	Accufuser, Accufuser Plus, and Standard Procedure Kit
Common Name:	Elastomeric Infusion Pump System & Kit
Classification Name:	Elastomeric Infusion Pump
Classification Panel:	80 – General Hospital and Personal Use Device
Regulation Number:	Class II, 880.5725
Procode:	MEB
Original and previously cleared 510(k)s:	K003915, K023098, K033039

Summary of Safety and Effectiveness for the Accufuser, Accufuser Plus and Standard Procedure Kit

This submission is intended to notify the Food and Drug Administration that McKinley Medical LLC intends to market a modification to an existing device (K033039) called the Accufuser, Accufuser Plus and Standard Procedure Kit.

The modifications to the existing device consist of an addition of an indication for use.

This device was previously cleared per 510(k)s K003915, K023098 and K033039.

Supporting predicate devices demonstrating substantial equivalence is McKinley's beeLINE system & standard procedure kit (K042228) and the I-Flow Elastomeric Pump (K040337).

The cleared indications for use for the Accufuser/Accufuser Plus system are as follows:

The Accufuser and Accufuser Plus systems are intended 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. The Accufuser Plus is also intended for patient-controlled infusion using the integrated bolus button. General infusion uses include pain management for preoperative, perioperative, and postoperative surgery.

The Accufuser and Accufuser Plus systems are also intended for continuous and/or intermittent delivery of medication (such as local anesthetics or narcotics) to surgical wound sites and/or close proximity to nerves for preoperative, perioperative and postoperative regional anesthesia and pain management. Routes of administration may be intraoperative, perineural or percutaneous.

The Accufuser/Accufuser Plus system is suitable for use as an ambulatory device and is intended for use in the hospital, home environment or alternative care sites.

The added indication for use is as follows:

The Accufuser and Accufuser Plus systems are intended to significantly decrease narcotic use and pain when used to deliver local anesthetics to surgical wound sites or close proximity to nerves when compared with narcotic only pain management.

Summary Description of the Accufuser System

The Accufuser device consists of an elastomeric balloon medication reservoir with a flow rate-controlling administration set. The pressure that pumps the fluid is derived from the strain energy of the elastomeric membrane that is forced to expand when the pump is filled. The administration set includes a flow restrictor component with controlled internal diameter and length. The flow rate at which medication is dispensed from the system is a function of the pressure applied to the medication and the dimensions of the

flow restrictor component. The medication may be dispensed from the system continuously and/or intermittently.

The size of the reservoir and the amount of flow restriction are determined to yield a variety of product codes with differing infusion volumes and flow rates. The physician prescribes for a patient a flow rate and reservoir size based on the individual patient needs.

Administration sets may incorporate a bolus feature, which may be used alone or in conjunction with basal (continuous) flow. The bolus device consists of a dosage reservoir that is filled when activated manually. After the bolus device has been activated, the bolus volume is infused at a controlled flow rate. The bolus device is integrated into the administration set and allows patient-controlled administration of medication as needed.

A procedure kit option provides various components that facilitate setup and use of the Accufuser system.

The Accufuser system is intended for single patient use.

Conclusion: The modified Accufuser system does not raise any new safety and efficacy concerns when compared to similar devices that are already legally marketed. The Accufuser, Accufuser Plus, and Standard Procedure Kit are substantially equivalent to the named predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

APR 14 2005

Mr. Ralph D. Cooey
Chief Operations Officer
McKinley Medical LLC
4080 Youngfield Street
Wheat Ridge, Colorado 80033

Re: K050770
Trade/Device Name: Accufuser; Accufuser Plus; Standard Procedure Kits
Regulation Number: 880.5725
Regulation Name: Infusion Pump
Regulatory Class: II
Product Code: MEB
Dated: March 23, 2005
Received: March 25, 2005

Dear Mr. Cooey:

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.

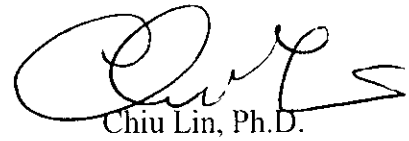
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish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

8. Indications for Use Statement

Applicant: McKinley Medical LLC

510(k) Number (if known): _____

Device Name: Accufuser; Accufuser Plus; Standard Procedure Kits

Indications for Use:

The Accufuser and Accufuser Plus systems are intended 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. The Accufuser Plus is also intended for patient-controlled infusion using the integrated bolus button. General infusion uses include pain management for preoperative, perioperative, and postoperative surgery.

The Accufuser and Accufuser Plus systems are also intended for continuous and/or intermittent delivery of medication (such as local anesthetics or narcotics) to surgical wound sites and/or close proximity to nerves for preoperative, perioperative and postoperative regional anesthesia and pain management. Routes of administration may be intraoperative, perineural or percutaneous.

The Accufuser/ Accufuser Plus system is suitable for use as an ambulatory device and is intended for use in the hospital, home environment or alternative care sites.

The Accufuser and Accufuser Plus systems are intended to significantly decrease narcotic use and pain when used to deliver local anesthetics to surgical wound sites or close proximity to nerves when compared with narcotic only pain management.

Prescription Use ____XX___ (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)

[signature]

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

510(k) Number: K052774