K060933

510(k) Summary

MAY - 9 2006

Date of Submission: April 20, 2006

Submitter: Apex Medical Technologies, Inc.
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Contact: Whitney A. Williams
Development Engineer
Apex Medical Technologies, Inc.

Trade Name: Solace Post-Operative Pain Relief Infusion System

Common Name: Infusion Pump

Classification: Pump, Infusion, Elastomeric (21CFR 880.5725, Product Code MEB, MRZ)

Comparison Device: Baxter Infusor, K051253
I-Flow Pump, K040337
Baxter Pain Management System, K002380
I-Flow PainBuster Infusion Kit, K982946
I-Flow Nerve Block Infusion Kit, K984502
I-Flow Soaker Catheter, K043456

Device Description: Apex's Solace Post-Operative Pain Relief Infusion System is a single use infusion device, which incorporates an elastomeric bladder with a permanently attached fixed flow rate administration set designed to deliver medication at a constant flow rate. The medication enters the body via a catheter, which is inserted near a surgical wound site then positioned under the skin. The pump attaches to the catheter at the distal end of the administration set. The catheter consists of four design options (same as predicate devices).

Standard epidural catheter: 3 radial holes at the distal end with an approximate 0.5-inch infusion segment.

Catheter with infusion segment: a modified epidural with multiple holes at the distal end with 2.5 inch, 5.0 inch and 10 inch infusion segments. The holes are arranged so that the flow is evenly distributed along the infusion segment.

The system may also incorporate a dual port site for dual catheter use.

Indications for Use: The Solace Infusion System is intended for continuous infusion of medications directly into the intraoperative site for post-operative pain management. Additional routes of administration include subcutaneous and intramuscular infusion.

Intended Use: The Solace Infusion System is for single patient use only.

The Solace Infusion System is suitable for use as an ambulatory device and is intended for use in the hospital, home environment or alternative care site.

The Solace Infusion System is not intended for intravenous, intra-arterial or epidural drug delivery.

The Solace Infusion System is not intended for the delivery of blood, blood products or lipids or fat emulsions.

Technological Characteristics: The Solace Infusion System and predicate devices are single-use disposable elastomeric infusion pumps designed to deliver solution at a constant flow rate (0.5 ml to 10 ml per hour) via a permanently attached set. The maximum fill volume range is 65 ml to 500 ml (Baxter maximum volume is 270 ml).

The Solace pump utilizes flow restrictive tubing to achieve +/- 15% flow accuracy over the infusion system.

The I-Flow pump utilizes a glass capillary and/or flow restrictive tubing to achieve +/- 15% flow accuracy over the infusion system.

The Baxter pump utilizes a glass capillary to achieve +/- 10% flow accuracy over the infusion system.

The Solace pump balloon is spherical and is made from a proprietary synthetic polyisoprene formulation that contains no natural rubber or accelerators.

The I-Flow and Baxter pump balloons are cylindrical. The I-Flow pump balloon is made from synthetic polyisoprene and natural rubber. The Baxter pump balloon is made from a proprietary synthetic polyisoprene formulation.

Conclusion: The Solace Post-Operative Pain Relief Infusion System is substantially equivalent to the existing pain management kits.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY - 9 2006

Apex Medical Technologies, Incorporated
C/O Mr. Robert Mosenkis
Responsible Third Party Official
CITECH
5200 Butler Pike
Plymouth Meeting, Pennsylvania 19462-1298

Re: K060933
Trade/Device Name: Solace Post-Operative Pain Relief Infusion System
Regulation Number: 21 CFR 880.5725
Regulation Name: Infusion Pump
Regulatory Class: II
Product Code: MEB
Dated: April 21, 2006
Received: April 24, 2006

Dear Mr. Mosenkis:

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.

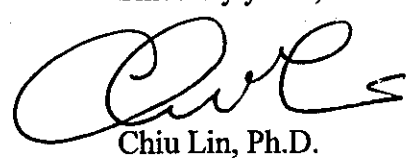
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish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

Applicant: Apex Medical Technologies, Inc.

510(k) Number (if known): K964933

Device Name: Solace Post-Operative Pain Relief Infusion System

Indications for Use:

1. The Solace Infusion System is intended for continuous infusion of medications directly into the intraoperative site for post-operative pain management. Additional routes of administration include subcutaneous and intramuscular infusion.

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)

Anthony D. Watson

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

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