K061356

ADVANCED INFUSION

920 East University Drive • Suite D202 • Tempe, Arizona 85281
480.768.9747 • fax: 480.894.5288
www.advancedinfusion.com

JUL - 3 2006

510(k) SUMMARY – Safety and Effectiveness

Polyurethane Infusion Catheter

Owner:

Advanced Infusion, Inc.
920 E. University Drive, Suite D202
Tempe, Arizona 85281
(480) 768-9747
(480) 894-5288 fax

Contact:

James Christensen
Vice President Operations
(909) 394-4916

Date Prepared: May 5, 2006

Trade Name: *Polyurethane* Infusion Catheter
Common Name: Infusion Catheter
Classification Name: Catheter, Conduction, Anesthetic
(21 CFR 868.5120, Product Code BSO)

Predicate Devices:

K021964 – Alpha Infusion Pump and Catheters
K042246 – Multi Drip Infusion Catheter
K003915 – Accufuser and Accufuser Plus
K993691 – ARROWg^{+}ard Blue Plus Antimicrobial Multi Lumen Catheter

Device Description:

The *Polyurethane* Infusion Catheter consists of two design options:

Alpha Cath™ open end style catheter: this style catheter consists of a length of tubing which functions as a flow restrictor. The proximal end of the tubing has a stainless needle for insertion into the Alpha Infusion Pump. The distal end of the tubing contains axial slit ports near the distal tip which are designed to infuse medication in case the end of the catheter becomes blocked.

Multi Drip® closed end style catheter: this style catheter consists of a length of tubing which functions as a flow restrictor. The proximal end of the tubing has a stainless needle for insertion

K061356

ADVANCED INFUSION

920 East University Drive • Suite D202 • Tempe, Arizona 85281
480.768.9747 • fax: 480.894.5288
www.advancedinfusion.com

510(k) SUMMARY – Safety and Effectiveness

into the Alpha Infusion Pump. The distal end of the tubing has a series of tiny ports along the distal portion of the catheter which are designed to spread medication along an infusion zone.

Intended Use:

The *Polyurethane* Infusion Catheters are intended for use with the *Alpha Infusion Pump* for the infusion of a local anesthetic into a surgical site or body cavity, post-operatively, for the relief of pain. The *Polyurethane* Infusion Catheter are intended for use in the hospital or by an ambulatory patient.

Technological Comparison:

The *Polyurethane* Infusion Catheters are the same as the current *Alpha Cath*™ and *Multi Drip*™ Infusion Catheters except that the catheter material has been changed from PVC to medical grade polyurethane.

Conclusion:

The *Polyurethane* Infusion Catheters are substantially equivalent to the existing *Alpha Cath*™ and *Multi Drip*™ Infusion Catheter product lines.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL - 3 2006

Mr. James Christensen
Vice President Operations
Advanced Infusion, Incorporated
920 East University Drive, Suite D202
Tempe, Arizona 85281

Re: K061356
Trade/Device Name: Polyurethane Infusion Catheters
Regulation Number: 880.5725
Regulation Name: Infusion Pump
Regulatory Class: II
Product Code: MEB
Dated: May 5, 2006
Received: May 15, 2006

Dear Mr. Christensen:

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

4. INDICATIONS FOR USE

510(k) Number (if known): K061356

Device Name: *Polyurethane* Infusion Catheters

Indications for Use:

The *Polyurethane* Infusion Catheters are intended for use with the *Alpha Infusion Pump* for the infusion of a local anesthetic into a surgical site or body cavity, post-operatively, for the relief of pain. The *Polyurethane* Infusion Catheters are intended for use in the hospital or by an ambulatory patient.

Prescription Use X AND/OR Over-The-Counter Use
(Part 21 CFR 801 Subpart D) (Part 21 CFR 807 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Anesthesiology, General Hospital
Dental Devices

K061356