K061661

ADVANCED INFUSION

466 W. Arrow Hwy. • Unit F • San Dimas, California 91773
909.394.4916 • fax 909.305.0295
www.advancedinfusion.com

OCT 18 2006

510(k) SUMMARY – Safety and Effectiveness

STA Cath® *Attachable* 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:
June 12, 2006

Trade Name:
STA Cath® *Attachable* Infusion Catheter
Common Name:
Infusion Pump
Classification Name:
Infusion Pump
(21 CFR 880.5725, Product Code MEB)

Predicate Devices:
K021964 – Alpha Infusion Pump and Catheters
K042264 – Multi Drip® Infusion Catheters
K003915 – Accufuser and Accufuser Plus
K040260 – Chronic Hemodialysis Catheter
K030020 – HemoSplit Long-Term Hemodialysis Catheter
K020577 – Applied Ureteral Catheter
K990500 – Ultramer Coude Foley Catheter

Device Description:
The *STA Cath*® *Attachable* Infusion Catheter is an open end style catheter similar to the *Alpha Cath*™ Infusion Catheter. This catheter consists of a length of PVC 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.

The distal end of the catheter has a short length of tubing attached to it. A loop of monofilament extends beyond both ends of this attached tube, and is used by the physician to draw a 4-0 suture, placed at an attachment site in the patient, through the attached tube in order to temporarily hold the catheter in place.

ADVANCED INFUSION™

466 W. Arrow Hwy. • Unit H • San Dimas, California 91773
909.394.4916 • fax: 909.305.0895
www.advancedinfusion.com

510(k) SUMMARY – Safety and Effectiveness

Intended Use:

The *STA Cath® Attachable* Infusion Catheter is 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 *STA Cath® Attachable* Infusion Catheter is intended for use in the hospital or by an ambulatory patient.

Technological Comparison:

There is no new technology added in the construction of the *STA Cath® Attachable* Infusion Catheter compared to the *Alpha Cath™* Infusion Catheter. The difference between the *STA Cath® Attachable* Infusion Catheter and the *Alpha Cath™* Infusion Catheter is that the *STA Cath® Attachable* Infusion Catheter incorporates a feature which enables the catheter to be temporarily attached to body tissues.

The attachment feature on the *STA Cath® Attachable* Infusion Catheter function similarly to the attachment features on other catheters such as the suture holes on the connectors of hemodialysis catheters, the implantable cuffs on hemodialysis and central venous catheters, the balloons on Foley catheters, and the pigtails on urethral catheters. All of these retention features hold the catheter temporarily in place during use of the catheter.

Conclusion:

The *STA Cath® Attachable* Infusion Catheter is substantially equivalent to the existing *Alpha Cath™* Infusion Catheter in design and operation and is substantially equivalent to other catheters such as Foley catheters which use a temporary means to hold the catheter in place during use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Mr. James Christensen
Vice President Operations
Advanced Infusion, Infusion
466 West Arrow Highway, Unit H
San Dimas, California 91773

OCT 1 8 2006

Re: K061661
Trade/Device Name: STA Cath® Attachable Infusion Catheter
Regulation Number: 21 CFR 880.5725
Regulation Name: Infusion Pump
Regulatory Class: II
Product Code: MEB
Dated: September 22, 2006
Received: September 25, 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.

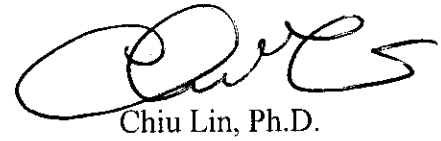
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish 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) 276-0120. 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 (240) 276-3150 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):_____

Device Name: *STA Cath® Attachable* Infusion Catheter

Indications for Use:

The *STA Cath® Attachable* Infusion Catheter is 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 *STA Cath® Attachable* Infusion Catheter is 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)

...ion Sign-Off)
...ion of Anesthesiology, General Hospital,
...ection Control, Dental Devices
...) Number: K061661