

20. Statement of Indications for Use

INDICATIONS FOR USE

510(k) Number (if known): _____

Device Name: Alpha Infusion Pump

Indications for Use:

The Alpha Infusion Pump is intended for intravenous, intra-arterial, subcutaneous, or epidural infusion of medications or fluids requiring continuous delivery at controlled infusion rates. Medications or fluids are intended to be delivered percutaneously through a catheter.

The Alpha Infusion Pump is suitable for use as an ambulatory device and is intended for use in the home environment but not limited to use in the home environment.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use X

OR

Over-The-Counter Use _____



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

510(k) Number K2192551

OCT 27 1999

K 992551

19. 510(k) Summary

510(k) SUMMARY – Safety and Effectiveness

Alpha Infusion Pump

The proposed device, the Alpha Infusion Pump, claims substantial equivalence in intended use and operation to the Baxter Intermate LV Elastomeric Infusion Device (K922382) and the I-Flow PainBuster Infusion System (K980558). Both are elastomeric chamber infusion pump intended to deliver medications or fluids to a patient by an intravenous, intra-arterial, subcutaneous, or epidural route. These pumps are ambulatory, external, disposable infusion pumps which deliver medication or fluids percutaneously to the patient via a catheter. They control flow rate using a flow restrictor.

The proposed device, the Alpha Infusion Pump, claims substantial equivalence in intended use to the Burrion Ambulatory Drug Delivery System (K896422), the Sgarlato Laboratories Pain Control Infusion Pump (K990101), and the McKinley Medical OutBound Disposable Syringe Infusor (K982256). These infusion pumps differ from the Alpha Infusion Pump only in the method used to pressurize the medication or fluid contained within the pump.

The proposed device, the Alpha Infusion Pump, claims substantial equivalence in intended use to the McKinley Medical OutBound PCA Pain Management System (K982256) and the Breg Pain Care 2000 (K983454). These infusion systems provide for the delivery of a bolus of medication on patient demand through a percutaneous catheter.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 27 1999

Mr. James Christensen
Advanced Infusion, Incorporated
6200 South McClintock #6
Tempe, Arizona 85283

Re: K992551
Trade Name: Alpha Infusion Pump
Regulatory Class: II
Product Code: FPA
Dated: July 27, 1999
Received: July 30, 1999

Dear Mr. Christensen:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to 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). 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 (Pre-market Approval), 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 895. A substantially equivalent determination assumes compliance with the Good Manufacturing Practice for Medical Devices: General (GMP) regulation (21 CFR Part 820) and that, through periodic GMP inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your pre-market notification submission does not affect any

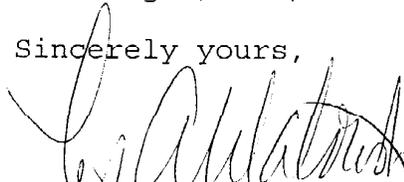
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obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 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 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4692. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "<http://www.fda.gov/cdrh/dsmamain.html>".

Sincerely yours,



Timothy A. Ulatowski
Director
Division of Dental, Infection Control
and General Hospital Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure