K040337

MAY 2 4 2004

Appendix E
Summary of Safety and Effectiveness

510(K) - SUMMARY OF SAFETY AND EFFECTIVENESS

February 9, 2004

Submitter: I-Flow Corporation
20202 Windrow Drive
Lake Forest, CA 92630

Contact: Shane Noehre
Director, Regulatory Affairs
I-Flow Corporation

Trade Names: ON-Q, PainBuster, C-bloc, Eclipse, C-Series, Easypump, Homepump

Classification Name: Pump, Infusion, Elastomeric

Existing Device: I-Flow Elastomeric Pump

Device Description: The current package labeling of the I-Flow Elastomeric Pump does not reference specific types of surgeries or potential benefits. This 510(k) proposes a labeling change that would reference the specific type(s) of surgery and potential benefits that are supported by published clinical studies.

Conclusion: The I-Flow Elastomeric Pump was used in the published clinical studies. The device was used according to FDA cleared indications for use (i.e. intraoperative or perineural local anesthetic delivery to relieve pain at the surgical site). I-Flow believes this change would not impact safety or efficacy and is supported by published clinical studies in widely known and esteemed journals.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 2 4 2004

Mr. Shane Noehre
Director, Regulatory Affairs
I-Flow Corporation
20202 Windrow Drive
Lake Forest, California 92630

Re: K040337
Trade/Device Name: I-Flow Elastomeric Pump
Regulation Number: 880.5725
Regulation Name: Infusion Pump
Regulatory Class: II
Product Code: MEB
Dated: May 18, 2004
Received: May 19, 2004

Dear Mr. Noehre:

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.

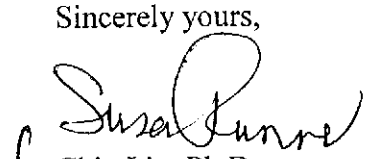
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish 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 (301) 594-4618. 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/dsma/dsmamain.html

Sincerely yours,



for 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

Indications for Use

510(k) Number (if known): K040337

Device Name: I-Flow Elastomeric Pump

Indications For Use:

1. The I-Flow Elastomeric Pump is intended for continuous and/or intermittent infusion of medications for general infusion use, including antibiotic delivery, chemotherapy and pain management. Routes of administration include the following: intravenous, intra-arterial, subcutaneous, intramuscular and epidural.
2. The I-Flow Elastomeric Pump is 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.
3. The I-Flow Elastomeric Pump is also 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 ___X___ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (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)

Irene Nawaz for ADW 5/21/04
(Division Sign-Off)
Division of Anesthesiology, General Hospital,
Infection Control, Dental Devices

510(k) Number: K040337