K043456

JAN 11 2005

SPECIAL 510(K) – SUMMARY OF SAFETY AND EFFECTIVENESS

Submitter:	I-Flow Corporation
Contact:	Shane Noehre Director, Regulatory Affairs I-Flow Corporation
Catheter Names:	I-Flow Catheter, Soaker Catheter, Fenestrated Catheter, Epidural Catheter
Common Name:	Catheter
Classification Name:	Catheter, Conduction, Anesthetic
Existing Device:	*I-Flow Catheter* (K991543, K994374 and K022869)
Device Description:	The *I-Flow Catheter* consists of three design options which can utilize infusion segments ranging from epidural to 10 inches (same as the predicate devices with the exception of the 10 inch infusion segment): Standard epidural catheter: 3 radial holes at the distal end with an approximate 0.5 inch infusion segment. Fenestrated Catheter: a modified epidural catheter with multiple holes at the distal end up to a 10 inch infusion segment Soaker Catheter: a modified epidural catheter with multiple holes at the distal end up to a 10 inch infusion segment. This version of the *I-Flow Catheter* contains a hollow fiber along the inner lumen or along the outside diameter of the distal end of the catheter to provide even distribution of medication along the infusion segment.
Technology Comparison:	The new 10 inch *I-Flow Catheter* model utilizes the exact same technology as the existing *I-Flow Catheter* product line.
Conclusion:	The new 10 inch *I-Flow Catheter* model is substantially equivalent to the existing *I-Flow Catheter* product line.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN 11 2005

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

Re: K043456
Trade/Device Name: I-Flow Catheter
Regulation Number: 21 CFR 868.5120
Regulation Name: Anesthesia Conduction Catheter
Regulatory Class: II
Product Code: BSO
Dated: December 10, 2004
Received: December 15, 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 (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/dsma/dsmamain.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

Indications for Use

510(k) Number (if known): K043456

Device Name: I-Flow Catheter / Soaker Catheter

Indications For Use:

1. With I-Flow Corporation's ON-Q, PainBuster and C-bloc pain management kits; and
2. As a stand alone device to provide continuous or intermittent delivery of medication (such as local anesthetics or narcotics) to surgical wound sites and/or close proximity to nerves. Routes of administration may be intraoperative, percutaneous, epidural or perineural. The Soaker version of the I-Flow Catheter is contraindicated for the epidural space.

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)

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

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