NOV 3 0 2005

510(K) – SUMMARY OF SAFETY AND EFFECTIVENESS

Submitter: I-Flow Corporation

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

Catheter Names: ON-Q SilverSoaker Catheter,
Common Name: Catheter

Classification Name: Catheter, Conduction, Anesthetic

Existing Device: *ON-Q Catheter* (K043456, previously identified as I-Flow Catheter)

Device Description: The *ON-Q SilverSoaker Catheter* consists of two design options:

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 *ON-Q SilverSoaker Catheter* contains a hollow fiber along the inner lumen of the catheter to provide even distribution of medication along the infusion segment.

This 510(k) adds an antimicrobial agent which may destroy or inhibit the growth of microorganisms on both the inner and outer surfaces of the catheter. The antimicrobial agent is intended to reduce the possibility that the catheter may become microbially compromised. The antimicrobial agent is not intended to be used as a treatment for existing infections.

Technology Comparison: The *ON-Q SilverSoaker Catheter* utilizes an antimicrobial agent which is similar to existing technology currently legally marketed.

Conclusion: The *ON-Q SilverSoaker Catheter* is substantially equivalent to the existing *ON-Q Catheter* product line and predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NOV 30 2005

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

Re: K051401
Trade/Device Name: ON-Q Catheter
Regulation Number: 868.5120
Regulation Name: Anesthesia Conduction Catheter
Regulatory Class: II
Product Code: BSO
Dated: November 21, 2005
Received: November 22, 2005

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.

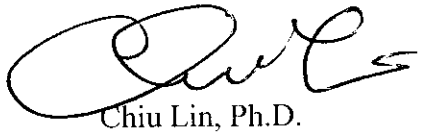
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish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

Indications for Use

510(k) Number (if known): K051401

Device Name: ON-Q SilverSoaker Catheter

Indications For Use:

1. The ON-Q SilverSoaker Catheter is intended to provide continuous or intermittent delivery of medication (such as local anesthetics or narcotics) to or around surgical wound sites for preoperative, perioperative and postoperative pain management. The ON-Q SilverSoaker Catheter is contraindicated for the epidural space and in neonatal populations.
2. The ON-Q SilverSoaker Catheter contains an antimicrobial agent which may destroy or inhibit the growth of microorganisms on both the inner and outer surfaces of the catheter. The antimicrobial agent is intended to reduce the possibility that the catheter may become microbially compromised. The antimicrobial agent is not intended to be used as a treatment for existing infections.

Prescription Use ___X___ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 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

510(k) Number: K051401