OCT 25 1999

K991543

SUMMARY OF SAFETY AND EFFECTIVENESS

Trade Name: ***Intra Op Catheter***

Common Name: Anesthetic Catheter

Classification Name: Anesthesia Conduction Catheter

Classification Panel: Anesthesiology

All questions and/or comments concerning this document should be made to:

Robert J. Bard, Esq., R.A.C.
Vice President of Regulatory and Legal Affairs

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

Telephone: 949.206.2700
Fax: 949.206.2600

1.0 GENERAL INFORMATION

1.1 Statement of Equivalence

1.1.1 The ***Intra Op Catheter*** is substantially equivalent to the (1) Teleflex Medical (TFX) Epidural Catheter (K840202, originally submitted by Aries) (2) the B. Braun Perifix Set (K813186) and (3) the Epimed Internation FETH-R_KATH catheter.

1.1.2 The ***Intra Op Catheter*** package may include components that are legally marketed (either pre-amendment devices or devices that have been granted permission to market via premarket notification regulation).

2.0 PHYSICAL SPECIFICATIONS AND DESCRIPTIONS

2.1 Description of the *Intra Op Catheter*

2.1.1 The ***Intra Op Catheter*** is identical to the Teleflex Medical (TFX) Epidural Catheter (K840202, originally submitted by Aries Medical) with the exception of a hollow fiber in the inner diameter of the distal end of the catheter.

2.1.1.1 ***Intra Op Catheter*** is manufactured by TFX using their current plastic formulation.

2.1.1.2 The catheter has a closed end tip with multiple holes arranged radially along the lateral surface at the distal end of the device.

[1]SE = Substantially Equivalent

2.1.2 The catheter package may contain a "T" Peel catheter over needle or a catheter connector (e.g.Touhy Borst) in addition to the catheter defined herein.

2.2 **Product Configuration**

2.2.1 The Catheter

2.2.1.1 The catheter is designed to be distributed in two basic configurations.

2.2.1.1.1 As shown in the catheter drawing (Dwg. No. 1120741 found in Appendix A), Detail G depicts the proximal end of the catheter with a catheter connector (Touhy Borst type) attached.

2.2.1.1.2 An alternate configuration with a bonded or insert molded luer lock catheter connector is also shown in the drawing.

3.0 OPERATIONAL SPECIFICATIONS AND DESCRIPTIONS

3.1

4.0 BIOLOGICAL SPECIFICATIONS

4.1

4.2 Biological testing is in conformance with ISO 10993 Part 1 for fluid path components.

4.3 The ***Intra Op Catheter*** is categorized as follows:

4.3.1 Device Category: External Communicating Device.

4.3.2 Body Contact: Tissue/Bone/Dentin Communicating

4.3.3 Contact Duration: Prolonged (24 hours to 30 days).

5.0 CHEMICAL AND DRUG SPECIFICATIONS

5.1 Compatibility

5.1.1 There are no specific drugs referenced in the labeling for the ***Intra Op Catheter***.

5.1.2 The ***Intra Op Catheter*** is intended for use with general local anesthetics and narcotic medications.

5.2 Drug Stability

5.2.1 There are no drugs included in the ***Intra Op Catheter***.

6.0 INTENDED USE

6.1 The ***Intra Op Catheter*** is intended to provide continuous or intermittent delivery of local anesthetics or narcotics to surgical wound sites and nerve trunks outside of the epidural space. Routes of administration may be either, intraoperative, intramuscular, subcutaneous or percutaneous.

6.2 The catheter is single patient use only.

7.0 LABELS AND LABELING

7.1 I-Flow Corporation believes the proposed labels and labeling, where appropriate, meets the requirements of 21 CFR Part 801 as it relates to a determination of intended use and adequate directions for use.

8.0 STANDARDS

8.1 There are currently no standards established for anesthesic catheters.

9.0 PACKAGING

9.1 The catheter is packaged in either a Tyvek pouch or a form/fill/seal tray.

10.0 STERILIZATION INFORMATION

10.1 The method of sterilization is Ethylene oxide gas or radiation

11.0 COMPARISON TO LEGALLY MARKETED DEVICES

11.1 The ***Intra Op Catheter*** is substantially equivalent to the (1) Teleflex Medical (TFX) Epidural Catheter (K840202, originally submitted by Aries) (2) the B. Braun Perifix Set (K813186) and (3) the Epimed Internation FETH-R_KATH catheter.

11.2 Device Descriptions

11.2.1 Comparisons

11.2.1.1 The device under review and its predicates are closed end with lateral/radial side holes.

11.2.2 Materials

11.2.2.1 The ***Intra Op Catheter's*** fluid path materials are in conformance with ISO 10993 Part 1.

11.2.3 Based upon the data presented in this section, I-Flow Corporation has determined that the Intra Op Catheter is substantially equivalent to the named predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 25 1999

Mr. Stanley E. Fry
Vice President
Regulatory Affairs/Quality Assurance
I-Flow Corporation
20202 Windrow Drive
Lake Forest, CA 92630

Re: K991543
Trade Name: Intraop Catheter
Regulatory Class: II
Product Code: MEB
Dated: September 3, 1999
Received: September 7, 1999

Dear Mr. Fry:

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 (Premarket 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 premarket notification submission does not affect any

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

510(k) Number (if known): K991543

Device Name: Intra Op Catheter

Indications for Use:

The ***Intra Op Catheter*** is intended to provide continuous or intermittent delivery of local anesthetics or narcotics to surgical wound sites and nerve trunks outside of the epidural space. Routes of administration may be either, intraoperative, intramuscular, subcutaneous or percutaneous.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of ~~Cardiovascular, Respiratory, and Neurological Devices~~
510(k) Number K991543

Prescription Use X
(Per 21 CFR 801.109)

OR

Over-The-Counter Use _____

(Optional Format 1-2-96)

(Division Sign-Off)
Division of Dental, Infection Control, and General Hospital Devices
510(k) Number K991543