

MAR - 3 2000

K 994374

**Summary of Safety and Effectiveness**

Trade Name: ***Soaker 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:

Stanley E. Fry  
Vice President of Regulatory and Quality

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 ***Soaker Catheter*** is substantially equivalent to the (1) I-Flow IntraOp Catheter (K991543), (2) Teleflex Medical (TFX) Epidural Catheter (K840202, originally submitted by Aries), (3) B. Braun Perifix Set (K813186) and (4) the Epimed International FETH-R\_KATH catheter (K981329).
- 1.1.2 The ***Soaker 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) such as an introducer needle or dressing.

**2.0 PHYSICAL SPECIFICATIONS AND DESCRIPTIONS**

**2.1 Description of the *Soaker Catheter***

- 2.1.1 The ***Soaker Catheter*** is identical to the predicate IntraOp Catheter (K991543). This premarket notification adds an additional model to the *Soaker Catheter* family of catheters.
- 2.1.2 The ***Soaker Catheter*** consists of a Teleflex Medical (TFX) Epidural Catheter (K840202, originally submitted by Aries Medical) with the insertion of a hollow fiber membrane in the inner diameter of the distal end of the catheter.
  - 2.1.2.1 The catheter has a closed end tip with multiple holes arranged radially along the lateral surface at the distal end of the device.

## 2.2 Product Configuration

2.2.1 The following **Soaker Catheter** models will be available:

- 2.2.1.1 S0605: 20 GA with 6.5 cm (2.5 in.) infusion segment (K991543).
- 2.2.1.2 S1205: 20 GA with 12.5 cm (5.0 in.) infusion segment.
- 2.2.1.3 Each of the catheter sizes will be available as a separate catheter with a currently marketed catheter connector (a Touhy Borst type is an example of any acceptable connector) or an attached luer lock connector. The connectors will meet the ANSI specifications conical connectors.

2.2.2 The **Soaker Catheter** may consist of a kit that includes components that are legally marketed (either pre-amendment devices or devices that have been granted permission to market via premarket notification regulation).

2.2.2.1 Examples of the kit components include the following:

- 2.2.2.1.1 Teleflex Medical (TFX) "T" peel catheter over needle 18 GA X 2 ½" - 3 ½" or
- 2.2.2.1.2 Johnson & Johnson Bioclusive dressing.

2.2.3 The **Soaker Catheter** may be used in I-Flow's Pain Management Systems such as K982946 and K984502.

## 3.0 BIOLOGICAL SPECIFICATIONS

- 3.1 All materials in the catheter are identical in formulation to materials currently being used in other products with the same or similar uses and have a long history of use in those devices.
- 3.2 Biological testing is in conformance with ISO 10993 Part 1 for fluid path components.

## 4.0 CHEMICAL AND DRUG SPECIFICATIONS

- 4.1 Drug Compatibility and Stability
  - 4.1.1 There are no specific drugs referenced in the labeling for the **Soaker Catheter**.
  - 4.1.2 There are no drugs included in the **Soaker Catheter**.

## 5.0 INTENDED USE

- 5.1 The **Soaker Catheter** is intended to be used as follows:
  - 5.1.1 With I-Flow Corporation's PainBuster, ON-Q and Nerve Block pain management kits; and
  - 5.1.2 As a stand alone device to provide continuous or intermittent delivery of local anesthetics or narcotics to surgical wound sites and/or close proximity to nerves outside of the epidural space. Routes of administration may be intraoperative or percutaneous.
- 5.2 The catheter is single patient use only.

## 6.0 LABELS AND LABELING

- 6.1 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.

## 7.0 STANDARDS

- 7.1 There are currently no standards established for anesthetic catheters.

## 8.0 PACKAGING

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

## 9.0 COMPARISON TO LEGALLY MARKETED DEVICES

- 9.1 The **Soaker Catheter** is substantially equivalent to the (1) I-Flow IntraOp Catheter submitted in K991543, (2) Teleflex Medical (TFX) Epidural Catheter (K840202, originally submitted by Aries) (3) the B. Braun Perifix Set (K813186) and (4) the Epimed International FETH-R\_KATH catheter.

### 9.2 Device Descriptions

#### 9.2.1 Comparisons

- 9.2.1.1 This submission is intended to notify the Federal Food and Drug Administration that I-Flow Corporation intends to add an additional model to the family of **Soaker Catheters** formerly referred to as the IntraOp Catheter (K991543). The new model is virtually identical to the predicate 2.5 inch Soaker Catheter except that the new model will have a 5.0 inch infusion segment.

- 9.2.1.2 All the catheters provide a catheter connector device similar to a Touhy Borst connector or a molded luer lock connector.

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



**MAR - 3 2000**

Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

Mr. Stanley E. Fry  
Vice President of Regulatory and Quality  
I-Flow Coproration  
20202 Windrow Drive  
Lake Forest, California 92630

Re: K994374  
Trade Name: Soaker Catheter  
Regulatory Class: II  
Product Code: FRN  
Dated: October 23, 1999  
Received: December 27, 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

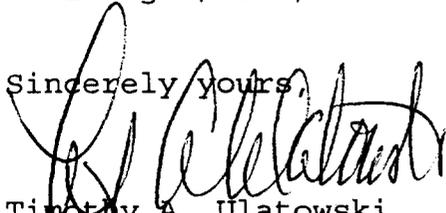
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the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

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) 594-4690. 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): K994374

Device Name: Soaker Catheter

**Indications for Use:**

The **Soaker Catheter** is intended to be used as follows:

1. With I-Flow Corporation's PainBuster, ON-Q and Nerve Block pain management kits; and
2. As a stand alone device to provide continuous or intermittent delivery of local anesthetics or narcotics to surgical wound sites and/or close proximity to nerves outside of the epidural space. Routes of administration may be intraoperative or percutaneous.

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

\_\_\_\_\_  
Concurrence of CDRH, Office of Device Evaluation (ODE) \_\_\_\_\_

Prescription Use X  
(Per 21 CFR 801.109)

OR

Over-The-Counter Use \_\_\_\_\_

*Patricia Cucchi*

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

510(k) Number K994374

(Optional Format 1-2-96)