3/4/99

K984502

1.0 GENERAL INFORMATION

1.1 Purpose of Submission

1.1.1 This submission is intended to notify the Federal Food and Drug Administration that I-Flow Corporation intends to market a new product line to be called the Nerve Block Infusion Kit.

1.1.2 Trade Name: Nerve Block Infusion Kit

1.1.3 Common Name: Elastomeric Infusion Pump Kit

1.1.4 Classification Name: Pump, Infusion, Elastomeric

1.1.5 Classification Panel: General Hospital and Personal Use Device

1.2 Statement of Equivalence

1.2.1 The Nerve Block Infusion Kit is substantially equivalent in total or in part to the following: the I-Flow PainBuster Infusion Kit (K980558, K982946), the Sgarlato Pain Control Infusion Pump (PCIP) (K896422), the I-Flow Homepump C-Series (K944692), the B. Braun Continuous Nerve Block Set (pre-amendment device) and the McKinley Outbound Syringe Infuser (K982256).

1.2.2 The Nerve Block Infusion Kit includes components that are legally marketed (either pre-amendment devices or devices that have been granted permission to market via premarket notification regulation).

1.2.3 The pumps used in the Nerve Block Infusion Kit are identical in design and materials to the pumps used in the PainBuster Infusion Kit.

1.3 Definitions (from Taber's Cyclopedic Medical Dictionary, 1997)

1.3.1 Nerve Block: The induction of regional anesthesia by preventing sensory nerve impulses from reaching the centers of consciousness. This is usually done on a temporary basis, by using chemical or electrical means. In the former case, it is accomplished by injecting an anesthetic solution, such as procaine, around the nerve but at some distance, or by anesthetizing nerve endings in the region itself (infiltration).

2.0 PHYSICAL SPECIFICATIONS AND DESCRIPTIONS

2.1 Description of the Nerve Block Infusion Kit

2.1.1 The Nerve Block Infusion Kit is nearly identical to the I-Flow PainBuster Infusion Kit with the exception of a new intended use, the addition of three new pump models and the addition of three new kit components (insulated Tuohy needle, hemostasis valve assembly and hookup wire).

2.1.2 The kit is comprised of an elastomeric infusion pump (K944692) and various components such as catheter, needle, syringe, dressing, tape, gauze, hemostasis valve assembly, hookup wire and accessories such as carry case, power ring and clothing attachment clip (E-Clip).

2.1.2.1 The PainBuster kit contains all the above components except for the insulated Tuohy needle, hemostasis valve assembly and hookup wire.

2.1.3 The Nerve Block Infusion Kit is intended to provide continuous infusion of a local anesthetic near a nerve for regional anesthesia and pain management for pre-operative, perioperative and postoperative general and orthopedic surgery. Additional routes of administration include percutaneous, subcutaneous, epidural and into the intraoperative (soft tissue / body cavity) site and synovial cavity.

2.1.4 The Nerve Block pump is a disposable device intended for single patient use.

2.1.5 The Nerve Block pump is suitable for use as an ambulatory device and is intended for use in the hospital, home environment or alternative care sites.

2.2 **Product Configuration**

2.2.1 The Nerve Block kit models are available in fill volumes from 50 to 500 ml and flow rates from 0.5 to 10 ml/hr.

2.2.2 Each model consists of a kit with a Nerve Block pump and the following optional components/accessories:

2.2.2.1 Catheter, needle, hemostasis valve assemlby, hookup wire, syringe, dressing, carry case, E-clip, antiseptic skin swabs, tape, gauze and power ring.

2.3 **Components and Materials**

All fluid path components of the Nerve Block pump are identical to the fluid path components of the PainBuster pump.

2.4 **Pumping Mechanism**

2.4.1 The pressure that pumps the fluid comes from the strain energy of the elastomeric membranes which are forced to expand when the pump is filled.

2.4.2 The administration set consists of fixed diameter flow control tubing or glass orifice.

2.5 **Power Requirements**

2.5.1 The Nerve Block pump is a mechanical pump that utilizes elastomeric membranes for power. No additional external power source is required.

3.0 OPERATIONAL SPECIFICATIONS AND DESCRIPTIONS

3.1 **Standard Operating Conditions:**

Priming/Residual Volume:	<= 10	500 ml volume
	<= 9	270 ml volume
	<= 4	125 ml volume
	<= 3	65 ml volume
Operating Temperature:	31°C skin temperature (90°F)	
Test Solution:	0.9% NaCl	
Operating Pressure:	14 to 7 psi pressure source	
Head Height:	16"	
Accuracy:	±15% at 95% confidence interval	

3.2 **Flow Rate Performance Data**: Testing occurred at standard operating conditions. Testing occured at nominal fill volumes for each model. All models produced an average flow rate within the ±15% accuracy claim.

3.3 **Safety / Alarm Functions**

3.3.1 The Nerve Block pump provides a continuous fixed flow and as such is not subject to fluid runaway conditions similar to that of some electronic pumps. This device contains no alarms or indicators.

4.0 BIOLOGICAL SPECIFICATIONS

4.1 Biological testing is in conformance with ISO 10993 Part 1 for all fluid path components of the Nerve Block pump.

5.0 CHEMICAL AND DRUG SPECIFICATIONS

5.1 Compatibility

5.1.1 There are no specific drugs referenced in the labeling for the Nerve Block Infusion Kit.

5.1.2 The Nerve Block Infusion Kit is intended for use with general local anesthetics and epidural medications.

6.0 INTENDED USE

6.1 The Nerve Block Infusion Kit is intended to provide continuous infusion of a local anesthetic near a nerve for regional anesthesia and pain management for pre-operative, perioperative and postoperative general and orthopedic surgery. Additional routes of infusion include percutaneous, subcutaneous, epidural and into the intraoperative (soft tissue / body cavity) site and synovial cavity.

6.2 The Nerve Block pump is single patient use only.

6.3 No testing has been conducted to determine the efficacy of the Nerve Block pump for the delivery of blood, blood products, lipids or fat emulsions. The Nerve Block pump is not intended for the delivery of blood, blood products, lipids or fat emulsions.

6.4 The Nerve Block pump is suitable for use as an ambulatory device and is intended for use in the hospital, home environment or alternative care sites.

7.0 STANDARDS

7.1 There are currently no standards established for elastomeric infusion pumps.

8.0 PACKAGING

8.1 Packaging is suitable for either radiation or ETO sterilization.

9.0 STERILIZATION INFORMATION

9.1 The methods of sterilization are ETO gas.

10.0 COMPARISON TO LEGALLY MARKETED DEVICES

10.1 The Nerve Block Infusion Kit has similar routes of administration and components as the following predicate devices: the B. Braun Continuous Nerve Block Set , PainBuster Infusion Kit, Sgarlato Pain Control Infusion Pump (PCIP), Homepump C-Series and McKinley Outbound Syringe Infuser.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR - 4 1999

Robert J. Bard, Esq., R.A.C.
Vice President Regulatory and Legal Affairs
I-Flow Corporation
20202 Window Drive
Lake Forest, California 92630

Re: K984502
Trade Name: Nerve Block Infusion Kit
Regulatory Class: II
Product Code: MEB
Dated: December 17, 1998
Received: December 18, 1998

Dear Mr. Bard:

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): _____

Device Name: Nerve Block Infusion Kit

Indications for Use:

The Nerve Block Infusion Kit is intended to provide continuous infusion of a local anesthetic near a nerve for regional anesthesia and pain management for pre-operative, perioperative and postoperative general and orthopedic surgery. Additional routes of infusion include percutaneous, subcutaneous, epidural and into intraoperative sites.

(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 Dental, Infection Control,
and General Hospital Devices
510(k) Number K984502

Prescription Use ✓ OR Over-The-Counter Use _____
(Per 21 CFR 801.109)

(Optional Format 1-2-96)