I-FLOW
CORPORATION

20202 Windrow Drive
Lake Forest, CA 92630
(800) 448-3569 (714) 206-2700
Fax (714) 206-2600

K980558

MAY 28 1998

SUMMARY OF SAFETY AND EFFECTIVENESS

February 11, 1998

Trade Name: PainBuster

Common Name: Elastomeric Infusion Pump

Classification Name: Pump, Infusion, Elastomeric

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

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

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

Telephone: 714.206.2700
Fax: 714.206.2600

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 an intraoperative site infusion kit, the PainBuster™ Infusion System, that utilizes legally marketed components for a new intended use.

1.2 Statement of Equivalence

1.2.1 The PainBuster Infusion System is a kit which includes components that are legally marketed (either pre-amendment devices or devices that have been granted permission to market via premarket notification regulation).

1.2.2 The PainBuster Infusion System is substantially equivalent in intended use to the Pain Control Infusion Pump (PCIP) (K896422) distributed by Sgarlato Laboratories, Inc.

1.2.2.1 The Sgarlato PCIP kit contains an infusion pump produced by Burron/B. Braun, B. Braun catheter and Jelco needle.

1.2.2.2 The catheter and needle included in the PainBuster kit are separately purchased pre-amendment or 510(k) devices similar to the devices in the Sgarlato PCIP kit.

1.2.2.2.1 An example of the catheter included in the PainBuster kit is the B. Braun Perifix® Epidural Catheter Set.

1.2.2.2.2 An example of the needle included in the PainBuster kit is the Jelco™ Catheter Introducer Needle.

1.2.2.2.3 The PainBuster pump is substantially equivalent to the Homepump C-Series (K944692) and Homepump Eclipse (K932740) marketed by I-Flow Corporation.

1.2.2.3 The PainBuster pump's design is nearly identical to the original Homepump C-Series, see section 2.1 below.

2.0 PHYSICAL SPECIFICATIONS AND DESCRIPTIONS

2.1 Description of Device

2.1.1 The PainBuster Infusion System is a kit that is comprised of an elastomeric infusion pump, a catheter and a needle.

2.1.2 The PainBuster pump is the Homepump C-Series with a new intended use. The pump design is identical to the original Homepump C-Series except as follows:

2.1.2.1 The PainBuster pump utilizes the same soft PVC shell that the Homepump Eclipse uses.

2.1.2.2 The two (2) outer natural latex bladders have been replaced by a single thicker natural latex bladder.

2.1.2.3 The PainBuster pump is intended to be used with a catheter that is included with the kit.

2.2 Product Configuration

2.2.1 Models

2.2.1.1 P065005: 65 ml volume, 0.5 ml/hr flow rate

2.2.1.2 P125015: 125 ml volume, 1.5 ml/hr flow rate

2.2.1.3 P125020: 125 ml volume, 2.0 ml/hr flow rate

2.2.2 Each model consists of a kit with the following components:

2.2.2.1 (1) PainBuster pump.

2.2.2.2 (1) Catheter

2.2.2.2.1 20 G catheter, 11 to 40 in. length, polyamide or nylon or FEP (fluorinated ethylene propylene) polymer.

2.2.2.2.2 A catheter connector is included to connect the catheter to the distal luer of the administration set.

2.2.2.2.3 The B. Braun Perifix® Epidural Catheter Set is an example of the type of catheter that may be used with the PainBuster Infusion System.

2.2.2.2.3.1 Product code: EC20-0

2.2.2.2.3.2 510(k) number: K813186

2.2.2.3 (1) Needle:

2.2.2.3.1 14 to 18G, 1 ½ to 2 ¼ in. length, stainless steel.

2.2.2.3.2 The needle may be a catheter over needle as in the Jelco™ example below.

2.2.2.3.3 The Jelco™ Catheter Introducer Needle is an example of the type of catheter introducer needle that may be used with the PainBuster Infusion System.

2.2.2.3.3.1 Product code: 4058

2.2.2.4 (1) Directions for Use (DFU)

2.3 **Components and Materials**

All the components used in the PainBuster pump are identical to those used in the Homepump Eclipse or Homepump C-Series.

The PainBuster Infusion System is a disposable device intended for single use.

3.0 OPERATIONAL SPECIFICATIONS AND DESCRIPTIONS

3.1 **Standard Operating Conditions**:

Priming Volume:	less than 5.0 ml
Residual Volume:	less than 5.0 ml
Operating Temperature	31°C (skin temperature)
Test Solution:	0.9% NaCl
Operating Pressure:	9 to 14 psi
Head Height:	16"
Accuracy:	±15% at 95% confidence interval

3.2 **Flow Rate Performance Data**: Testing occurred at 31°C and at the nominal head height of 16".

	65ml x 0.5ml/hr	125ml x 2.0ml/hr
Average Flow Rate	0.48 ml/hr	1.98 ml/hr
Std. Dev.	0.02	0.05
n	27	26

65ml x 0.5ml/hr: A twenty seven (27) piece sample produced an average flow rate of 0.48 ml/hr. The resulting average is well within it's ±15% accuracy claim. The fastest infusion had an average flow rate of 0.53 ml/hr and the slowest infusion had an average flow rate of 0.41 ml/hr.

125ml x 2.0ml/hr: A twenty six (26) piece sample produced an average flow rate of 1.98 ml/hr. The resulting average is well within it's ±15% accuracy claim. The fastest infusion had an average flow rate of 2.05 ml/hr and the slowest infusion had an average flow rate of 1.83 ml/hr.

3.3 **Back Pressure Comparison:** Testing was performed on the Homepump Eclipse 65ml x 0.5ml/hr and 100ml x 2.0ml/hr to determine the effects of back pressure on the flow rate. Testing occurred at the nominal head height of 16", at a head height of 42" and at 3.1 psi. Ten samples at each back pressure were tested. The test results for flow rate at each pressure for each product are summarized in the following table.

	65ml x 0.5ml/hr			100ml x 2.0ml/hr		
Test Pressure	16" HH	42" HH	3.1 psi	16" HH	42" HH	3.1 psi
Average Flow Rate (ml/hr)	0.51	0.49	0.45	1.96	1.77	1.79
Std. Dev.	0.03	0.02	0.03	0.09	0.08	0.08
n	15	10	10	15	15	15

The average decrease in flow rates produced by the increased back pressure is as expected.

3.4 **Drug Delivery Comparison:** The Homepump Eclipse 65ml x 0.5ml/hr has been tested to assess how a 5% Dextrose solution affects flow rate. The performance of the system is affected by the viscosity or density of a solution. The flow rate was measured at 31°C. The resulting data is presented below.

Note: Local anesthetics have densities similar to normal saline (e.g. 1.0035 for Bupivacaine).

	65ml x 0.5ml/hr	
	Saline	5% Dextrose
Average Flow Rate (ml/hr)	0.49	0.46
Std.Dev.	0.02	0.02
n	30	15

65ml x 0.5ml/hr: The 5% Dextrose solution flow rate was 6% slower than the normal saline solution.

Product labeling includes a statement as to delivery times and the possible deviation from nominal.

3.5 **Catheters and PICC Lines:** The Homepump Eclipse 65ml x 0.5ml/hr has been tested to assess how a 20 G x 60 cm PICC line and 23 G x 28 cm epidural catheter affects flow rate. The tests were performed at room temperature and 31°C at the nominal head height of 16". The results are summarized in the table below.

		Average (ml/hr)	Std Dev.	Maximum (ml/hr)	Minimum (ml/hr)
PICC Line	Room Temp.	0.41	0.02	0.44	0.39
	31°C	0.51	0.03	0.58	0.48
Epidural Catheter	Room Temp.	0.38	0.04	0.45	0.32
	31°C	0.53	0.02	0.56	0.49

The PICC line and epidural catheter had no effect on flow.

4.0 BIOLOGICAL SPECIFICATIONS

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

5.0 CHEMICAL AND DRUG SPECIFICATIONS

5.1 Compatibility

5.1.1 There are no specific drugs referenced in the labeling for the PainBuster Infusion System.

5.1.2 The PainBuster Infusion System is intended for use with general local anesthetics.

6.0 INTENDED USE

6.1 The PainBuster is intended to provide continuous infusion of a local anesthetic directly into the intraoperative site for postoperative pain management.

6.2 The PainBuster is intended to deliver pain medication percutaneously via an administration set attached to a catheter.

6.3 The PainBuster is not intended for epidural, subcutaneous or vascular drug delivery.

6.4 The PainBuster is single use only.

6.5 No testing has been conducted to determine the efficacy of the PainBuster for the delivery of blood, blood products or TPN. The PainBuster is not intended for the delivery of blood, blood products or TPN.

6.6 The PainBuster is suitable for use as an ambulatory device and is intended for use in the home environment but not limited to use in the home environment.

7.0 PACKAGING

7.1 The PainBuster kit components are packaged individually in either sterile Tyvek® pouches or sterile Form/Fill/Seal trays. The components of the kit are packaged in a sealed tray.

7.1.1 Packaging is suitable for either radiation or ETO sterilization.

8.0 STERILIZATION INFORMATION

Note: The catheter and needle components of the PainBuster Infusion System may be purchased non-sterile and packaged by I-Flow or sterile from the manufacture. The PainBuster pump and non-sterile purchased components shall be sterilized as follows:

8.1 The methods of sterilization are gamma radiation (Cobalt 60) or ETO gas.

9.0 COMPARISON TO LEGALLY MARKETED DEVICE

Note: The following summarizes the similarities and differences of the PainBuster Infusion System versus its predicate devices.

Comparison Element	PainBuster Infusion System (subject device)	SE[1] Homepump C-Series (K944692)	SE[1] Homepump Eclipse (K932740)	SE[1] PCIP (K896422)
Intended Use	To provide continuous infusion of a local anesthetic directly into the intraoperative site for postoperative pain management.	General infusion use.	General infusion use.	To provide continuous infusion of a local anesthetic directly into the surgical wound site for postoperative pain management.
Route of Administration	Percutaneous	Intravenous, intra-arterial, epidural or subcutaneous	Intravenous	Percutaneous
Specific Use	Primarily pain management, ambulatory, home therapy.	Primarily pain management, chemotherapy, ambulatory, home therapy.	Primarily ambulatory, home therapy.	Primarily pain management, ambulatory, home therapy.
Contraindications	Not intended for epidural, subcutaneous or vascular drug delivery. Not intended for delivery of blood, blood products or TPN.	Not intended for blood, blood products or TPN.	Not intended for delivery of blood, blood products or TPN.	Not intended for rapid infusions. Not intended for intravenous infusion.
Other	Disposable, Single Use Only	Disposable, Single Use Only	Disposable, Single Use Only	Disposable, Single Use Only
Description	Sold empty and capable of being filled via a fill port.	Sold empty and capable of being filled via a fill port.	Sold empty and capable of being filled via a fill port.	Sold empty and capable of being filled via a fill port.
Flow Rates	0.5, 1.5 or 2.0 ml/hr	0.5 to 500 ml/hr	50, 75, 100, 150 or 200 ml/hr	0.5, 1.0 or 2.0 ml/hr
Pump Type	Elastomeric Pump	Elastomeric Pump	Elastomeric Pump	Spring Driven Syringe Pump
Power Requirements	None	None	None	None
Pump Mechanism	Constant pressure is applied to the fluid reservoir.	Constant pressure is applied to the fluid reservoir.	Constant pressure is applied to the fluid reservoir.	Constant pressure is applied to the fluid reservoir.
Pressure Source	Strain energy of elastomeric membranes	Strain energy of elastomeric membranes	Strain energy of elastomeric membranes	Compression spring
Fluid Reservoir	Thermoplastic (Krayton) elastomeric membrane	Thermoplastic (Krayton) elastomeric membrane	Thermoplastic (Krayton) elastomeric membrane	Polypropylene plastic syringe
Administration Set	Integrated, flow control tubing	Integrated, flow control tubing	Integrated, flow control tubing	Integrated, flow control tubing
Flow Control	Consistent flow rate throughout the entire course of therapy is achieved by the combination of constant pressure and flow control tubing.	Consistent flow rate throughout the entire course of therapy is achieved by the combination of constant pressure and flow control tubing.	Consistent flow rate throughout the entire course of therapy is achieved by the combination of constant pressure and flow control tubing.	Consistent flow rate throughout the entire course of therapy is achieved by the combination of constant pressure and flow control tubing.
Safety / Alarm Functions	Fixed flow rate tubing prevents fluid runaway conditions. Each administration set is supplied with a clamp to stop the infusion if necessary.	Fixed flow rate tubing prevents fluid runaway conditions. Each administration set is supplied with a clamp to stop the infusion if necessary.	Fixed flow rate tubing prevents fluid runaway conditions. Each administration set is supplied with a clamp to stop the infusion if necessary.	Fixed flow rate tubing prevents fluid runaway conditions. Each administration set is supplied with a clamp to stop the infusion if necessary.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 28 1998

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

Re: K980558
Trade Name: PainBuster Infusion System
Regulatory Class: II
Product Code: MEB
Dated: April 27, 1998
Received: April 28, 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 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). 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 Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS 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"(21CFR 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/dsma/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

I-FLOW
CORPORATION

20202 Windrow Drive
Lake Forest, CA 92630
(800) 448-3569 (714) 206-2700
Fax (714) 206-2600

510(k) Number (if known): K980558

Device Name: PainBuster™ Infusion System

Indications for Use:

1. The PainBuster is intended to provide continuous infusion of a local anesthetic directly into the intraoperative (soft tissue / body cavity) site for postoperative pain management.
2. The PainBuster is intended to deliver pain medication percutaneously via an administration set attached to a catheter.
3. The PainBuster is single use only.
4. The PainBuster is suitable for use as an ambulatory device and is intended for use in the home environment but not limited to use in the home environment.
5. The PainBuster is not intended for epidural, subcutaneous or vascular drug delivery.
6. The PainBuster is not intended for chemotherapy drugs.
7. No testing has been conducted to determine the efficacy of the PainBuster for the delivery of blood, blood products or TPN. The PainBuster is not intended for the delivery of blood, blood products or TPN.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

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

Patricia Cascante
(Division Sign-Off)
Division of Dental, Infection Control,
and General Hospital Devices
510(k) Number K980558

(Optional Format 1-2-96)