NOV 18 1998

K982946

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SUMMARY OF SAFETY AND EFFECTIVENESS

August 19, 1998

Trade Name: PainBuster Infusion Kit

Common Name: Elastomeric Infusion Pump Kit

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

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Lake Forest, CA 92630

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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 extension to the current PainBuster product line, including labeling changes and additional models and components.

1.1.1.1 All models previously submitted under K980558 are included under this premarket notification.

1.1.2 Trade Name: PainBuster™ 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 PainBuster 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).

1.2.2 The PainBuster pump is an additional model to the Homepump elastomeric infusion pumps marketed by I-Flow Corporation (C-Series - K944692 and Eclipse - K932740).

1.2.3 The PainBuster Kit is substantially equivalent to the PainBuster Infusion System (K980558) marketed by I-Flow Corporation and the Pain Control Infusion Pump (PCIP) (K896422) marketed by Sgarlato Laboratories, Inc.

2.0 PHYSICAL SPECIFICATIONS AND DESCRIPTIONS

2.1 Description of Device

2.1.1 The PainBuster Infusion Kit is nearly identical to the PainBuster Infusion System (K980558) marketed by I-Flow Corporation except for some labeling changes and the addition of new models and optional components.

2.1.2 The kit is comprised of an elastomeric infusion pump (K944692) and various kit components such as catheter, needle, syringe, dressing, tape, gauze, carry case, Y Adapter, Power Ring and clothing attachment clip (E-Clip).

2.1.2.1 The Sgarlato kit contains all the above components except for the Power Ring and clothing attachment clip.

2.1.2.2 The original PainBuster Infusion System contained the pump, catheter and needle.

2.1.3 The PainBuster pump is intended to attach to the kit catheter at the distal end of the administration set to provide continuous infusion of a local anesthetic directly into the intraoperative site for general surgery for postoperative pain management.

2.1.4 The PainBuster is single patient use only.

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

2.1.6 See Appendix A for drawings and Appendix B and C for labeling of the PainBuster Infusion Kit.

2.2 Product Configuration

See Appendix A for drawings and Appendix B and C for labeling.

2.2.1 The following additional PainBuster models will be available:

2.2.1.1 P060020: 50/65 ml volume, 2.0 ml/hr flow rate

2.2.1.2 P110005: 100/125 ml volume, 0.5 ml/hr flow rate

2.2.1.3 P125050: 100/125 ml volume, 5.0 ml/hr flow rate

2.2.1.4 P270010: 250/270 ml volume, 1.0 ml/hr flow rate

2.2.1.5 P270020: 250/270 ml volume, 2.0 ml/hr flow rate

2.2.1.6 P270050: 250/270 ml volume, 5.0 ml/hr flow rate

2.2.1.7 P270100: 250/270 ml volume, 10.0 ml/hr flow rate

2.2.1.8 P270050Y: 250/270 ml volume, 5.0 ml/hr flow rate, dual catheter with Y adapter.

2.2.2 The following models were previously submitted under K980558.

2.2.2.1 P065005: 50/65 ml volume, 0.5 ml/hr flow rate

2.2.2.2 P125015: 100/125 ml volume, 1.5 ml/hr flow rate

2.2.2.3 P125020: 100/125 ml volume, 2.0 ml/hr flow rate

2.2.3 Each model above contains a variable fill volume designated by the slash between the two numbers. For example, model P060020 may be marketed as a 60 ml volume, 2.0 ml/hr flow rate. Alternatively, I-Flow may market the device as a 50 ml volume or 65 ml volume in which case the model number would be P050020 or P065020 respectively.

2.2.4 Models with flow rates from 0.5 ml/hr to 2 ml/hr are for small wound sites while flow rates from 5 ml/hr to 10 ml/hr are for larger wounds.

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

2.2.5.1 PainBuster pump.

2.2.4.11.2 The Kling® Conforming Gauze manufactured by Johnson and Johnson is an example of the type of gauze which may be used in the PainBuster Kit.

2.2.4.11.2.1 Model number: JJ6923

2.2.4.12 Power Ring (optional):

2.2.4.12.1 The Power Ring manufactured by I-Flow Corporation is fitted over the syringe to ease filling the pump. See schematic in Appendix A.

2.3 Components and Materials

All the pumps used in the PainBuster Kit are currently available models of the Homepump C-Series (K944692).

All the components used in the PainBuster pump are identical to those used in the original PainBuster submitted under K980558.

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

3.0 OPERATIONAL SPECIFICATIONS AND DESCRIPTIONS

3.1 Standard Operating Conditions:

Priming/Residual Volume (ml):	<= 9 270 ml Vol
	<= 4 125 ml Vol
	<= 3 65 ml Vol
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, at the nominal head height of 16", using normal saline (0.9% NaCl). Testing occurred at nominal fill volume for each model. All models produced an average flow rate well within the ±15% accuracy claim.

	60 ml x 2 ml/hr	110 ml x 0.5 ml/hr	125 ml x 5 ml/hr	270 ml x 1 ml/hr	270 ml x 2 ml/hr	270 ml x 5 ml/hr	270 ml x 10 ml/hr
Average Flow Rate (ml/hr)	1.80	0.48	4.74	1.01	2.03	4.52	10.8
Std. Dev.	0.10	0.02	0.16	0.03	0.08	0.13	0.3
n	15	46	29	33	35	12	6

60 ml x 2 ml/hr: A fifteen (15) piece sample produced an average flow rate of 1.80 ml/hr. The fastest infusion had an average flow rate of 1.99 ml/hr and the slowest infusion had an average flow rate of 1.65 ml/hr.

110 ml x 0.5 ml/hr: A forty six (46) piece sample produced an average flow rate of 0.48 ml/hr. The fastest infusion had an average flow rate of 0.53 ml/hr and the slowest infusion had an average flow rate of 0.45 ml/hr.

125 ml x 5 ml/hr: A twenty nine (29) piece sample produced an average flow rate of 4.74 ml/hr. The fastest infusion had an average flow rate of 5.16 ml/hr and the slowest infusion had an average flow rate of 4.37 ml/hr.

270 ml x 1 ml/hr: A thirty three (33) piece sample produced an average flow rate of 1.01 ml/hr. The fastest infusion had an average flow rate of 1.07 ml/hr and the slowest infusion had an average flow rate of 0.94 ml/hr.

270 ml x 2 ml/hr: A thirty five (35) piece sample produced an average flow rate of 2.03 ml/hr. The fastest infusion had an average flow rate of 2.17 ml/hr and the slowest infusion had an average flow rate of 1.84 ml/hr.

270 ml x 5 ml/hr: A twelve (12) piece sample produced an average flow rate of 4.52 ml/hr. The fastest infusion had an average flow rate of 4.8 ml/hr and the slowest infusion had an average flow rate of 4.3 ml/hr.

270 ml x 10 ml/hr: A six (6) piece sample produced an average flow rate of 10.8 ml/hr. The fastest infusion had an average flow rate of 11.3 ml/hr and the slowest infusion had an average flow rate of 10.5 ml/hr.

3.3 **Back Pressure (Head Height) Comparison:** Approximately 0.57 psi pressure difference results per 16" head height. Thus, a 5.7% flow rate change may occur for each 16" head height difference from nominal assuming a 10 psi average bladder pressure of the pump.

3.4 **Drug Delivery Comparison:** Local anesthetics have densities similar to normal saline (e.g. 1.002 to 1.005 for Ropivacaine HCl vs. 1.0045 for normal saline) and should not affect flow rate. Product labeling includes a statement as to delivery times and the possible deviation from nominal due to drug viscosity.

3.5 **Safety / Alarm Functions**

3.5.1 The PainBuster pump provides a continuous fixed flow and as such is not subject to fluid runaway conditions similar to that of some electronic pumps.

3.5.2 The PainBuster pump will not be recommended for any application that exceeds the minimum internal pressure of the system.

3.5.3 If for any reason the patient needs to stop his or her infusions, each administration set is supplied with a pinch clamp to stop the infusion.

3.5.4 This device contains no alarms or indicators for flow other than visual.

3.5.5 This device contains no alarms or indicators to detect air in line or an occlusion.

4.0 BIOLOGICAL SPECIFICATIONS

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

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 Kit.

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

5.2 Drug Stability

5.2.1 There are no drugs included in the PainBuster Infusion Kit.

6.0 INTENDED USE

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

6.2 Additional routes of administration include percutaneous and subcutaneous infusion.

6.3 The PainBuster is not intended for intravenous, intra-arterial or epidural drug delivery.

6.4 The PainBuster is single patient use only.

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

6.6 The PainBuster is suitable for use as an ambulatory device and is intended for use in the hospital, home environment or alternative care sites.

7.0 PACKAGING

7.1 The PainBuster Kit consists of an inner pouch or tray with Tyvek® lid stock surrounded by a header bag with an ETO Tyvek® strip.

7.2 The PainBuster pump may be packaged in either a Tyvek® pouch or Form/Fill/Seal.

7.3 The PainBuster Kit components are placed in the inner tray or pouch.

7.4 Packaging is suitable for either radiation or ETO sterilization.

8.0 STERILIZATION INFORMATION

Note: The kit components of the PainBuster Infusion Kit 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.

Comparison Element	PainBuster Infusion Kit (subject device)	SE[1] PainBuster Infusion System (K980558)	SE[1] Sgarlato PCIP (K896422)	SE[1] Homepump C-Series (K944692)
Intended Use	To provide continuous infusion of a local anesthetic directly into the intraoperative site for general surgery for postoperative pain management.	To provide continuous infusion of a local anesthetic directly into the intraoperative site for postoperative pain management.	To provide continuous infusion of a local anesthetic directly into the surgical wound site for postoperative pain management.	General infusion use.
Route of Administration	Percutaneous and subcutaneous	Percutaneous	Percutaneous, subcutaneous and epidural	Intravenous, intra-arterial, epidural or subcutaneous
Specific Use	Pain management	Pain management	Primarily pain management, ambulatory, home therapy.	Primarily pain management, chemotherapy, ambulatory, home therapy.
Contraindications	Not intended for intravenous, intra-arterial or epidural drug delivery. Not intended for delivery of blood, blood products, lipids or fat emulsions.	Not intended for vascular or epidural drug delivery. Not intended for delivery of blood, blood products or TPN.	Not intended for rapid infusions. Not intended for intravenous infusion.	Not intended for blood, blood products or TPN.
Reuse Capability	Disposable, Single Patient 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.
Fill Volumes	50 to 270 ml	50 to 125 ml	50 to 100 ml	50 to 500 ml
Flow Rates	0.5, 1.0, 1.5, 2.0, 5.0 or 10.0 ml/hr	0.5, 1.5 or 2.0 ml/hr	0.5, 1.0 or 2.0 ml/hr	0.5 to 500 ml/hr
Pump Type	Elastomeric Pump	Elastomeric Pump	Spring Driven Syringe Pump	Elastomeric 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	Compression spring	Strain energy of elastomeric membranes
Fluid Reservoir	Thermoplastic (Krayton) elastomeric membrane	Thermoplastic (Krayton) elastomeric membrane	Polypropylene plastic syringe	Thermoplastic (Krayton) elastomeric membrane
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.

[1]SE = Substantially Equivalent

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

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NOV 18 1998

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

Re: K982946
Trade Name: PainBuster Infusion Kit
Regulatory Class: Unclassified
Product Code: MEB
Dated: August 20, 1998
Received: August 21, 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

K982946

Revised Indications for Use (Nov. 9, 1998)

510(k) Number (if known): K982946

Device Name: PainBuster™ Infusion Kit

Indications for Use:

1. The PainBuster is intended to provide continuous infusion of a local anesthetic directly into an intraoperative (soft tissue / body cavity) site for general surgery for postoperative pain management. Additional routes of administration include percutaneous and subcutaneous infusion.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

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

(Division Sign-Off)
Division of Dental, Infection Control, and General Hospital Devices
510(k) Number K982946

(Optional Format 1-2-96)