JUN 2 1 1999

K991513

I-FLOW CORPORATION

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SUMMARY OF SAFETY AND EFFECTIVENESS

April 29, 1999

Trade Name: Homepump C-Series and Homepump C-Series One•Step KVO

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 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 Purpose of Submission

1.1.1 This submission is intended to notify the Federal Food and Drug Administration that I-Flow Corporation is adding two new optional components to the Homepump C-Series (K944692).

1.1.1.1 Regulator (optional)

1.1.1.1.1 The optional regulator controls the decreasing pressure (14 to 9 psi) of the Homepump C-Series to a fixed 6.0 psi.

1.1.1.2 Flow Indicator (optional)

1.1.1.2.1 An optional flow indicator component incorporates a flow status column indicator with the glass orifice flow restrictor.

Note: The PainBuster Infusion Kit (K980558 and K982946), the On-Q Infusion Kit (K980558 and K982946) and the Nerve Block Infusion Kit (K984502) use the Homepump C-Series infusion pumps in their kits. Neither the regulator nor the flow indicator components change the intended use of the Homepump C-Series when used in the PainBuster, On-Q or Nerve Block Infusion Kits.

1.2 Statement of Equivalence

1.2.1 The Homepump C-Series is substantially equivalent to the existing I-Flow Homepump C-Series (K944692) and the 3M IV Flow Regulator (K896907).

2.0 PHYSICAL SPECIFICATIONS AND DESCRIPTONS

2.1 Description of Device

2.1.1 The Homepump C-Series is an elastomeric infusion pump with an integrated administration set.

2.1.2 The elastomeric membranes function as the fluid reservoir and the pressure source.

2.1.3 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.

2.1.4 The incorporation of fixed diameter flow control tubing or glass orifice combined with the elastomeric pressure source produces the desired flow rate.

2.2 Product Configuration

2.2.1 Homepump C-Series models are available in fill volumes from 50 to 500 ml and flow rates from 0.5 to 10 ml/hr. The One•Step KVO models of the Homepump C-Series have an optional Y-site and optional check valve attached to the distal end of the administration set.

2.2.2 The following accessories are available: carry case, E-clip and power ring.

2.3 Components and Materials

All fluid path materials are in compliance with ISO 10993 Part 1.

2.4 Power Requirements

2.4.1 The Homepump C-Series is a mechanical device that utilizes elastomeric membranes for power. No additional external power is required.

3.0 OPERATIONAL SPECIFICATIONS AND DESCRIPTIONS

3.1 Standard Operating Conditions:

Priming/Residual Volume:	<= 10 ml for 500 ml volume pump <= 9 ml for 270 ml volume pump <= 4 ml for 125 ml volume pump <= 3 ml for 65 ml volume pump
Operating Temperature:	31°C skin temperature (88°F)
Test Solution:	0.9% NaCl
Pressure Source:	6.0 psi
Head Height:	0"
Flow Rate Accuracy:	±10% at 95% confidence interval

3.2 **Flow Rate and Pressure Performance Data:** Testing occurred at standard operating conditions. All models produced an average flow rate and pressure within the ±10% accuracy claim.

3.3 Safety/Alarm Functions

3.3.1 The Homepump C-Series provides a fixed flow and as such is not subject to fluid runaway conditions similar to that of some electronic pumps.

3.3.2 This device contains no alarms for flow; however, each set may include an optional flow indicator component that indicates the flow status of the device.

3.3.3 This device contains no alarms or indicators to detect air in line or an occlusion; however, each set may include an optional, integrated air-eliminating filter.

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 Homepump C-Series.

6.0 INTENDED USE

6.1 The Homepump C-Series is intended for continuous infusion of medications for general infusion use, including chemotherapy and pain management. Routes of administration include intravenous, subcutaneous, intramuscular and epidural.

6.2 The KVO model of the Homepump C-Series is intended for general purpose drug and/or diluent delivery at a sufficient flow rate to maintain a patient IV line open (i.e. keep vein open). The Y adapter at the distal end of the administration set allows piggyback infusions. The routes of administration include intravenous, subcutaneous and intramuscular.

6.3 The Homepump C-Series is single patient use only.

6.4 The Homepump C-Series is suitable for use as an ambulatory device and is intended for use in the hospital, home environment or alternative care sites.

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

7.0 STANDARDS

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

8.0 PACKAGING

8.1 Packaging is suitable for radiation or ETO sterilization.

9.0 STERILIZATION

9.1 The methods of sterilization are gamma radiation (cobalt 60) or ETO gas.

10.0 COMPARISON TO LEGALLY MARKETED DEVICES

10.1 The Homepump C-Series has the same intended use and routes of administration as the originally submitted Homepump C-Series. The optional regulator of the Homepump C-Series is similar to the 3M IV Flow Regulator.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN 21 1999

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

Re: K991513
Trade Name: Homepump C-Series and Homepump C-Series One-Step KVO
Regulatory Class: II
Product Code: FPA
Dated: April 29, 1999
Received: April 30, 1999

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

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CORPORATION

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510(k) Number (if known): _____

Device Name: Homepump C-Series

Indications for Use:

1. The Homepump C-Series is intended for continuous infusion of medications for general infusion use, including chemotherapy and pain management. Routes of administration include intravenous, subcutaneous, intramuscular and epidural.
2. The KVO model of the Homepump C-Series is intended for general purpose drug and/or diluent delivery at a sufficient flow rate to maintain a patient IV line open (i.e. keep vein open). The Y-site at the distal end of the administration set allows piggy back infusions. The routes of administration include intravenous, subcutaneous and intramuscular.

Patricia Cuscinta

(Division Sign-Off)
Division of Dental, Infection Control,
and General Hospital Devices
510(k) Number K991513

(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)

(Optional Format 1-2-96)