USER:	**STEINBERG, SHERRI L (szs)**
FOLDER:	**K020660 - 70 pages (FOI:08003800)**
COMPANY:	**I-FLOW CORP. (IFLOW)**
PRODUCT:	**PUMP, INFUSION, ELASTOMERIC (MEB)**
SUMMARY:	**Product: HOMEPUMP, ECLIPSE, C-SERIES, PAINBUSTER, C-BLOC, ON-Q, EASYPUMP, ONE S**

DATE REQUESTED:	**Thu Dec 10 24:00:00 2009**
DATE PRINTED:	**Wed Jan 13 15:46:30 2010**
Note:	**Releasable Version**

Table of Contents

510KSUM - 4 pages	**1**
ADD TO FILE - 3 pages	**5**
CORRESPONDENCE - 4 pages	**8**
ORIGINAL - 48 pages	**12**
REVIEWER INFORMATION - 9 pages	**60**

SPECIAL 510(K) - SUMMARY OF SAFETY AND EFFECTIVENESS

March 15, 2002

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

Contact: Shane Noehre
Manager, Regulatory Affairs
I-Flow Corporation

Trade Name: I-Flow Variable Rate Elastomeric Pump

Common Name: Infusion Pump and Administration Set

Classification Name: Pump, Infusion

Existing Device: I-Flow Elastomeric Pump (K932740, K944692, K984502, K991513 and K992072)

Device Description: The I-Flow Variable Rate Elastomeric Pump consists of an elastomeric pressure source with an integrated administration line. This special 510(k) proposes a new component that incorporates a variable flow rate mechanism.

Technology Comparison: The Variable Flow Rate Component is identical to the one recently cleared under K020251.

Conclusion: The I-Flow Variable Rate Elastomeric Pump is substantially equivalent to the existing I-Flow Elastomeric Pump and the variable flow rate component cleared under K020251.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 2 0 2002

Ms. Shane Noehre
Manager, Regulation Affairs
I-Flow Corporation
20202 Windrow Drive
Lake Forest, California 92630

Re: K020660
Trade/Device Name: I-Flow Variable Rate Elastomeric Pump
Regulation Number: 880.5725
Regulation Name: Infusion Pump and Administration Sets
Regulatory Class: II
Product Code: MEB
Dated: February 26, 2002
Received: March 1, 2002

Dear Mr. Noehre:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and 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) that do not require approval of a premarket approval application (PMA). 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 (PMA), 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 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies.

You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 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 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4618. 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 Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer 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,

Susan Runner

for Timothy A. Ulatowski
Director
Division of Dental, Infection Control
and General Hospital Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K020660

I-Flow Corporation
20202 Windrow Drive
Lake Forest, CA 92630
Tel: 800.448.3569 or 949.206.2700
Fax: 949.206.2600
www.i-flowcorp.com

Ver/ 3 - 4/24/96

Applicant: I-Flow Corporation

510(k) Number (if known): K020660

Device Name: I-Flow Variable Rate Elastomeric Pump

Indications For Use:

1. The I-Flow Variable Rate Elastomeric Pump is intended for continuous and/or intermittent infusion of medications for general infusion use, including antibiotic delivery, chemotherapy and pain management. Routes of administration include the following: intravenous, intra-arterial, subcutaneous, intramuscular and epidural.
2. The I-Flow Variable Rate Elastomeric Pump is also intended for continuous and/or intermittent delivery of medication (such as local anesthetics or narcotics) to surgical wound sites and/or close proximity to nerves for preoperative, perioperative and postoperative regional anesthesia and pain management. Routes of administration may be intraoperative, perineural or percutaneous.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Per 21 CFR 801.109)

(Optional Format 1-2-96)

(b) (6) [redacted]

(Division Sign-Off)
Division of Dental, Infection Control,
and General Hospital Devices
510(k) Number K020660

I-FLOW®
I-Flow Corporation
20202 Windrow Drive
Lake Forest, CA 92630
Tel: 800.448.3569 or 949.206.2700
Fax: 949.206.2600
www.i-flowcorp.com

K020660/A

March 15, 2002

Via Federal Express

Irene Naveau
FDA / CDRH
510(k) Document Mail Center (HFZ – 401)
9200 Corporate Blvd.
Rockville, Maryland 20850

FDA/CDRH/ODE/DHC
MAR 18 11 30 AM '02
RECEIVED

Dear Ms. Naveau:

Re: K020660

Per our discussion on March 15, 2002, I-Flow requests for the name of K020660 to be "I-Flow Variable Rate Elastomeric Pump". Please find attached a new Indications for Use and Summary page with this name.

Sincerely,

(b) (6) [redacted]

Shane Noehre
Manager, Regulatory Affairs
I-Flow Corporation
Tel: 949.206.2653
Fax: 949.206.2600
E-mail: shane.noehre@i-flowcorp.com

SKIP

8

I-Flow Corporation
20202 Windrow Drive
Lake Forest, CA 92630
Tel: 800.448.3569 or 949.206.2700
Fax: 949.206.2600
www.i-flowcorp.com

Ver/ 3 - 4/24/96

Applicant: I-Flow Corporation

510(k) Number (if known): K020660

Device Name: I-Flow Variable Rate Elastomeric Pump

Indications For Use:

1. The I-Flow Variable Rate Elastomeric Pump is intended for continuous and/or intermittent infusion of medications for general infusion use, including antibiotic delivery, chemotherapy and pain management. Routes of administration include the following: intravenous, intra-arterial, subcutaneous, intramuscular and epidural.
2. The I-Flow Variable Rate Elastomeric Pump is also intended for continuous and/or intermittent delivery of medication (such as local anesthetics or narcotics) to surgical wound sites and/or close proximity to nerves for preoperative, perioperative and postoperative regional anesthesia and pain management. Routes of administration may be intraoperative, perineural or percutaneous.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Per 21 CFR 801.109)

(Optional Format 1-2-96)

SPECIAL 510(K) - SUMMARY OF SAFETY AND EFFECTIVENESS

March 15, 2002

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

Contact: Shane Noehre
Manager, Regulatory Affairs
I-Flow Corporation

Trade Name: I-Flow Variable Rate Elastomeric Pump

Common Name: Infusion Pump and Administration Set

Classification Name: Pump, Infusion

Existing Device: I-Flow Elastomeric Pump (K932740, K944692, K984502, K991513 and K992072)

Device Description: The I-Flow Variable Rate Elastomeric Pump consists of an elastomeric pressure source with an integrated administration line. This special 510(k) proposes a new component that incorporates a variable flow rate mechanism.

Technology Comparison: The Variable Flow Rate Component is identical to the one recently cleared under K020251.

Conclusion: The I-Flow Variable Rate Elastomeric Pump is substantially equivalent to the existing I-Flow Elastomeric Pump and the variable flow rate component cleared under K020251.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 2 0 2002

Ms. Shane Noehre
Manager, Regulation Affairs
I-Flow Corporation
20202 Windrow Drive
Lake Forest, California 92630

Re: K020660
Trade/Device Name: I-Flow Variable Rate Elastomeric Pump
Regulation Number: 880.5725
Regulation Name: Infusion Pump and Administration Sets
Regulatory Class: II
Product Code: MEB
Dated: February 26, 2002
Received: March 1, 2002

Dear Mr. Noehre:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and 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) that do not require approval of a premarket approval application (PMA). 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 (PMA), 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 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies.

You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 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 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4618. 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 Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer 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,

Susan Runner

Timothy A. Ulatowski
Director
Division of Dental, Infection Control
and General Hospital Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

2

K020660

I-Flow Corporation
20202 Windrow Drive
Lake Forest, CA 92630
Tel: 800.448.3569 or 949.206.2700
Fax: 949.206.2600
www.i-flowcorp.com

Ver/ 3 - 4/24/96

Applicant: I-Flow Corporation

510(k) Number (if known): K020660

Device Name: I-Flow Variable Rate Elastomeric Pump

Indications For Use:

1. The I-Flow Variable Rate Elastomeric Pump is intended for continuous and/or intermittent infusion of medications for general infusion use, including antibiotic delivery, chemotherapy and pain management. Routes of administration include the following: intravenous, intra-arterial, subcutaneous, intramuscular and epidural.
2. The I-Flow Variable Rate Elastomeric Pump is also intended for continuous and/or intermittent delivery of medication (such as local anesthetics or narcotics) to surgical wound sites and/or close proximity to nerves for preoperative, perioperative and postoperative regional anesthesia and pain management. Routes of administration may be intraoperative, perineural or percutaneous.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Per 21 CFR 801.109)

(Optional Format 1-2-96)

(b) (6) [redacted]

(Division Sign-Off)
Division of Dental, Infection Control,
and General Hospital Devices
510(k) Number K020660

DEPARTMENT OF HEALTH AND HUMAN SERVICES Public Health Service

Food and Drug Administration
Center for Devices and
Radiological Health
Office of Device Evaluation
Document Mail Center (HFZ-401)
9200 Corporate Blvd.
Rockville, Maryland 20850

March 01, 2002

I-FLOW CORP.
20202 WINDROW DR.
LAKE FOREST, CA 92630
ATTN: SHANE NOEHRE

510(k) Number: K020660
Received: 01-MAR-2002
Product: HOMEPUMP, ECLIPSE, C-SERIES, PAINBUSTER, C-BLOC, ON-Q, EASYPUMP, ONE

The Center for Devices and Radiological Health (CDRH), Office of Device Evaluation (ODE), has received the Premarket Notification you submitted in accordance with Section 510(k) of the Federal Food, Drug, and Cosmetic Act (Act) for the above referenced product. We have assigned your submission a unique 510(k) number that is cited above. Please refer prominently to this 510(k) number in any future correspondence that relates to this submission. We will notify you when the processing of your premarket notification has been completed or if any additional information is required. YOU MAY NOT PLACE THIS DEVICE INTO COMMERCIAL DISTRIBUTION UNTIL YOU RECEIVE A LETTER FROM FDA ALLOWING YOU TO DO SO.

As a reminder, we would like to mention that FDA requires all 510(k) submitters to provide an indications for use statement on a separate page. If you have not included this indications for use statement in addition to your 510(k) summary (807.92), or a 510(k) statement (807.93), and your Truthful and Accurate statement, please do so as soon as possible. If the above mentioned requirements have been submitted, please do not submit them again. There may be other regulations or requirements affecting your device such as Postmarket Surveillance (Section 522(a)(1) of the Act) and the Device Tracking regulation (21 CFR Part 821). Please contact the Division of Small Manufacturers, International and Consumer Assistance (DSMICA) at the telephone or web site below for more information.

Please remember that all correspondence concerning your submission MUST be sent to the Document Mail Center (DMC)(HFZ-401) at the above letterhead address. Correspondence sent to any address other than the DMC will not be considered as part of your official premarket notification submission. Because of equipment and personnel limitations, we cannot accept telefaxed material as part of your official premarket notification submission, unless specifically requested of you by an FDA official. Any telefaxed material must be followed by a hard copy to the DMC (HFZ-401).

You should be familiar with the manual entitled, "Premarket Notification 510(k) Regulatory Requirements for Medical Devices" available from DSMICA. If you have other procedural or policy questions, or want information on how to check on the status of your submission (after 90 days from the receipt date), please contact DSMICA at (301) 443-6597 or its toll-free number (800) 638-2041, or at their Internet address http://www.fda.gov/cdrh/dsmamain.html or me at (301) 594-1190.

Sincerely yours,

Marjorie Shulman
Consumer Safety Officer
Premarket Notification Staff
Office of Device Evaluation

16

K020660

Special 510(k) – Device Modification

for the

Homepump

Marketed by I-Flow Corporation

FDA/CDRH/ODE/DMC
MAR 1 11 15 AM '02
RECEIVED

FDA Original

SKIS

1+0
II
17

CDRH SUBMISSION COVER SHEET

Date of Submission: February 26, 2002

FDA Document Number:

Section A Type of Submission

PMA	PMA Supplement	PDP	510(k)	Meeting
☐ Original submission ☐ Modular submission ☐ Amendment ☐ Report ☐ Report Amendment	☐ Regular ☐ Special ☐ Panel Track ☐ 30-day Supplement ☐ 30-day Notice ☐ 135-day Supplement ☐ Real-time Review ☐ Amendment to PMA Supplement	☐ Presubmission summary ☐ Original PDP ☐ Notice of intent to start clinical trials ☐ Intention to submit Notice of Completion ☐ Notice of Completion ☐ Amendment to PDP ☐ Report	☑ Original submission: ☐ Traditional ☑ Special ☐ Abbreviated ☐ Additional information: ☐ Traditional ☐ Special ☐ Abbreviated	☐ Pre-IDE meeting ☐ Pre-PMA meeting ☐ Pre-PDP meeting ☐ 180-day meeting ☐ Other (specify):

IDE	Humanitarian Device Exemption	Class II Exemption	Evaluation of Automatic Class III Designation	Other Submission
☐ Original submission ☐ Amendment ☐ Supplement	☐ Original submission ☐ Amendment ☐ Supplement ☐ Report	☐ Original submission ☐ Additional information	☐ Original submission ☐ Additional information	Describe submission:

RECEIVED FDA/CDRH/OEE/DMC MAR 1 11:15 AM '02

Section B Applicant or Sponsor

Company / Institution name: I-Flow Corporation

Establishment registration number: 2026095

Division name (if applicable):

Phone number (include area code): (949) 206-2700 ext. 2670

Street address: 20202 Windrow Drive

FAX number (include area code): (949) 206-2600

City: Lake Forest

State / Province: CA

Country: U.S.A.

Contact name: James J. Dal Porto

Contact title: Chief Operating Officer

Contact e-mail address: jim.dalporto@i-flowcorp.com

Section C Submission correspondent (if different from above)

Company / Institution name: I-Flow Corporation

Establishment registration number: 2026095

Division name (if applicable):

Phone number (include area code): (949) 206-2700 ext. 2653

Street address: 20202 Windrow Drive

FAX number (include area code): (949) 206-2600

City: Lake Forest

State / Province: CA

Country: U.S.A.

Contact name: Shane Noehre, RAC

Contact title: Manager, Regulatory Affairs

Contact e-mail address: shane.noehre@i-flowcorp.com

Section D1 — Reason for Submission — PMA, PDP, or HDE

- ☐ New device
- ☐ Withdrawal
- ☐ Additional or expanded indications
- ☐ Licensing agreement
- ☐ Process change
  - ☐ Manufacturing
  - ☐ Sterilization
  - ☐ Packaging
  - ☐ Other (specify below)
- ☐ Response to FDA correspondence:
  - ☐ Request for applicant hold
  - ☐ Request for removal of applicant hold
  - ☐ Request for extension
  - ☐ Request to remove or add manufacturing site
- ☐ Other reason (specify):
- ☐ Change in design, component, or specification:
  - ☐ Software
- ☐ Color Additive
  - ☐ Material
  - ☐ Specifications
- ☐ Other (specify below)
- ☐ Labeling change:
  - ☐ Indications
  - ☐ Instructions
  - ☐ Performance Characteristics
- ☐ Shelf life
- ☐ Trade name
- ☐ Other (specify below)
- ☐ Location change:
  - ☐ Manufacturer
  - ☐ Sterilizer
  - ☐ Packager
  - ☐ Distributor
- ☐ Report submission:
  - ☐ Annual or periodic
  - ☐ Post-approval study
  - ☐ Adverse reaction
  - ☐ Device defect
  - ☐ Amendment
- ☐ Change in ownership
  - ☐ Change in correspondent

Section D2 — Reason for Submission — IDE

- ☐ New device
- ☐ Addition of institution
- ☐ Expansion / extension of study
- ☐ IRB certification
- ☐ Request hearing
- ☐ Request waiver
- ☐ Termination of study
- ☐ Withdrawal of application
- ☐ Unanticipated adverse effect
- ☐ Notification of emergency use
- ☐ Compassionate use request
- ☐ Treatment IDE
- ☐ Continuing availability request
- ☐ Other reason (specify):
- ☐ Change in:
  - ☐ Correspondent
  - ☐ Design
  - ☐ Informed consent
  - ☐ Manufacturer
  - ☐ Manufacturing process
  - ☐ Protocol – feasibility
  - ☐ Protocol – other
  - ☐ Sponsor
- ☐ Report submission:
  - ☐ Current investigator
  - ☐ Annual progress
  - ☐ Site waiver limit reached
  - ☐ Final
- ☐ Response to FDA letter concerning:
  - ☐ Conditional approval
  - ☐ Deemed approved
  - ☐ Deficient final report
  - ☐ Deficient progress report
  - ☐ Deficient investigator report
  - ☐ Disapproval
  - ☐ Request extension of time to respond to FDA
  - ☐ Request meeting

Section D3 — Reason for Submission — 510(k)

- ☐ New device
- ☐ Additional or expanded indications
- ☐ Other reason (specify):
- ☐ Change in technology
- ☑ Change in design
- ☐ Change in materials
- ☐ Change in manufacturing process

Section E Additional Information on 510(k) Submissions

Product codes of devices to which substantial equivalence is claimed:

1 MEB	2	3	4
5	6	7	8

Summary of, or statement concerning, safety and effectiveness data:
☒ 510(k) summary attached
☐ 510(k) statement

Information on devices to which substantial equivalence is claimed:

510(k) Number	Trade or proprietary or model name	Manufacturer
1 K932740	1 Homepump Eclipse	1 I-Flow Corporation
2 K944692	2 Homepump C-Series	2 I-Flow Corporation
3 K984502	3 Nerve Block Infusion Kit	3 I-Flow Corporation
4 K991513	4 C-Series and KVO	4 I-Flow Corporation
5 K992072	5 Homepump Bolus	5 I-Flow Corporation
6 K020251	6 Paragon Variable Rate	6 I-Flow corporation

Section F Product Information — Applicable to All Applications

Common or usual name or classification name:
Infusion Pump and Administration Sets

Trade or proprietary or model name	Model number
1 Homepump, Eclipse, C-Series, PainBuster, C-bloc, ON-Q, Easypump, One-Step KVO	1 various
2	2
3	3
4	4
5	5

FDA document numbers of all prior related submissions (regardless of outcome):

1	2	3	4	5	6
7	8	9	10	11	12

Data included in submission: ☐ Laboratory testing ☐ Animal trials ☐ Human trials

Section G Product Classification — Applicable to All Applications

Product code: MEB
C.F.R. Section: 880.5725
Classification panel: General Hospital

Device class:
☐ Class I ☒ Class II
☐ Class III ☐ Unclassified

Indications (from labeling):
See Indications for Use page in submission.

Note: Submission of this information does not affect the need to submit a 2891 or 2891a Device Establishment Registration form.	FDA Document Number:

Section H Manufacturing / Packaging / Sterilization Sites Relating to a Submission

☒ Original ☐ Add ☐ Delete	FDA establishment registration number: 2026095	☒ Manufacturer ☐ Contract manufacturer	☐ Contract sterilizer ☐ Repackager / relabeler
Company / Institution name: I-Flow Corporation		Establishment registration number: 2026095	
Division name (if applicable):		Phone number (include area code): (949) 206-2700	
Street address: 20202 Windrow Drive		FAX number (include area code): (949) 206-2600	
City: Lake Forest	State / Province: CA		Country: U.S.A.
Contact name: Shane Noehre, RAC			
Contact title: Manager, Regulatory Affairs		Contact e-mail address: shane.noehre@i-flowcorp.com	
☐ Original ☐ Add ☐ Delete	FDA establishment registration number:	☐ Manufacturer ☐ Contract manufacturer	☐ Contract sterilizer ☐ Repackager / relabeler
Company / Institution name:		Establishment registration number:	
Division name (if applicable):		Phone number (include area code): ( )	
Street address:		FAX number (include area code): ( )	
City:	State / Province:		Country:
Contact name:			
Contact title:		Contact e-mail address:	
☐ Original ☐ Add ☐ Delete	FDA establishment registration number:	☐ Manufacturer ☐ Contract manufacturer	☐ Contract sterilizer ☐ Repackager / relabeler
Company / Institution name:		Establishment registration number:	
Division name (if applicable):		Phone number (include area code): ( )	
Street address:		FAX number (include area code): ( )	
City:	State / Province:		Country:
Contact name:			
Contact title:		Contact e-mail address:	

I-Flow Corporation
20202 Windrow Drive
Lake Forest, CA 92630
Tel: 800.448.3569 or 949.206.2700
Fax: 949.206.2600
www.i-flowcorp.com

SPECIAL 510(k): Device Modification

February 26, 2002

Via Federal Express

FDA/CDRH/ODE/DMC
MAR 1 11 15 AM '02
RECEIVED

Food and Drug Administration
Center for Devices and Radiological Health
510(k) Document Mail Center (HFZ – 401)
9200 Corporate Blvd.
Rockville, Maryland 20850

Reviewing Staff:

In accordance with §510(k) of the Federal Food, Drug, and Cosmetic Act and in conformance with Title 21 CFR §807.81, I-Flow Corporation is submitting this premarket notification for the *Homepump* prior to the introduction into interstate commerce for commercial distribution.

I-Flow intends to market a new optional component for the Homepump. This new component is intended to allow variable flow rates.

This Variable Flow Rate Component is identical to the one recently cleared under K020251. The only difference will be in the calibration of the flow control tubings for the Homepump pressure source vs. the Paragon pressure source.

The existing (unmodified) *Homepump* has been cleared under the following 510(k)s: K932740, K944692, K984502, K991513 and K992072.

No changes will be made to the indications for use, sterilization, fundamental scientific technology, packaging, labeling (except for clarification) or the pump (other than adding the variable rate controller).

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

Shane Noehre
Manager of Regulatory Affairs

Sincerely,

(b) (6) [redacted]

Shane Noehre, RAC
Manager, Regulatory Affairs
I-Flow Corporation
20202 Windrow Dr
Lake Forest, CA 92630
Tel: (949) 206-2653, Fax: (949) 206-2600
e-mail: shane.noehre@i-flowcorp.com

TABLE OF CONTENTS

Cover Letter ..... Page 1

Truthful and Accurate Statement ..... Page 3

Indications for Use ..... Page 4

Declaration of Conformity ..... Page 5

Summary of Safety and Effectiveness ..... Page 6

1.0 General Information ..... Page 7

2.0 Physical Specifications and Descriptions ..... Page 7

3.0 New Models ..... Page 9

4.0 Components and Materials ..... Page 9

5.0 Operational Specifications and Description ..... Page 10

6.0 Biocompatibility Specifications ..... Page 10

7.0 Chemical and Drug Specifications ..... Page 10

8.0 Indications for Use ..... Page 10

9.0 Labels and Labeling ..... Page 11

10.0 Standards ..... Page 11

11.0 Packaging ..... Page 11

12.0 Sterilization ..... Page 12

13.0 Comparison to Existing (Unmodified) Device ..... Page 12

Appendix A – Risk Assessment for the Variable Flow Component (DCD1121A)

Appendix B – Example Homepump Drawing

Appendix C – Example Homepump Labeling

Appendix D – Homepump Regulatory Documentation

PREMARKET NOTIFICATION
TRUTHFUL AND ACCURATE STATEMENT
(As required by 21 CFR 807.87(j))

I certify that, in my capacity as the Chief Operating Officer of I-Flow Corporation, I believe to the best of my knowledge, that all data and information submitted in the premarket notification for the Homepump are truthful and accurate and that no material fact has been omitted.

(b) (6) [redacted]

Signature

James J. Dal Porto, Chief Operating Officer

Name Title

I-Flow Corporation 2/27/02

Company Dated

Premarket Notification (510(k) Number)

I-Flow Corporation
20202 Windrow Drive
Lake Forest, CA 92630
Tel: 800.448.3569 or 949.206.2700
Fax: 949.206.2600
www.i-flowcorp.com

Ver/ 3 - 4/24/96

Applicant: I-Flow Corporation

510(k) Number (if known): _____

Device Name: Homepump

Indications For Use:

1. The Homepump is intended for continuous and/or intermittent infusion of medications for general infusion use, including antibiotic delivery, chemotherapy and pain management. Routes of administration include the following: intravenous, intra-arterial, subcutaneous, intramuscular and epidural.
2. The Homepump is also intended for continuous and/or intermittent delivery of medication (such as local anesthetics or narcotics) to surgical wound sites and/or close proximity to nerves for preoperative, perioperative and postoperative regional anesthesia and pain management. Routes of administration may be intraoperative, perineural or percutaneous.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Per 21 CFR 801.109)

(Optional Format 1-2-96)

DECLARATION OF CONFORMITY

As required by the risk analysis, all verification and validation activities will be performed by designated individuals and the results shall demonstrate that the predetermined acceptance criteria are met prior to the introduction into interstate commerce for commercial distribution.

The I-Flow Corporation manufacturing facilities are in conformance with the design control requirements as specified in 21 CFR 820.30 and the records are available for review.

(b) (6) [redacted] 2/27/02

Signature Dated

(b) (6) [redacted] 2/27/02

Signature Dated

James J. Dal Porto
Chief Operating Officer
I-Flow Corporation

Bill Porter
Vice President of Engineering / R&D
I-Flow Corporation

Verification and Validation activity will ensure the device meets the requisite design specifications and acceptance criteria and shall include the following:

1. Flow Rate Accuracy: (b) (4) [redacted] confidence interval.
2. Leak Testing: no leaks when pressurized to (b) (4) [redacted]
3. Residual Volume: < (b) (4) [redacted]
4. Bond Strength: ((b) (4) [redacted] (external manifold tubes), (b) (4) [redacted] (occluding tubes), (b) (4) [redacted] (flow control tubes).
5. Labeling: per section 9.0 of this submission.
6. Package Integrity: per section 11.0 of this submission.
7. Sterility: per section 12.0 of this submission.
8. Incoming Inspection: per the Risk Assessment.
9. Inprocess and Final Inspection: per the Risk Assessment.

Reference Documents

1. Risk Assessment for the variable flow component (DCD1121A)

SPECIAL 510(K) - SUMMARY OF SAFETY AND EFFECTIVENESS

January 23, 2002

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

Contact: Shane Noehre
Manager, Regulatory Affairs
I-Flow Corporation

Trade Name: Homepump

Common Name: Infusion Pump and Administration Set

Classification Name: Pump, Infusion

Existing Device: Homepump (K932740, K944692, K984502, K991513 and K992072)

Device Description: The Homepump consists of an elastomeric pressure source with an integrated administration line. This special 510(k) proposes a new component that incorporates a variable flow rate mechanism.

Technology Comparison: The Variable Flow Rate Component is identical to the one recently cleared under K020251.

Conclusion: The Homepump with Variable Flow Rate is substantially equivalent to the existing Homepump and the variable flow rate component cleared under K020251.

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 intends to make a device modification to our own legally marketed device. The change affects all our 510(k)s that utilize our Homepump (detailed in the section below). A new optional component for the Homepump will incorporate a variable flow rate component.

1.1.2 The existing (unmodified) Homepump has been cleared under the following 510(K)s:

- K932740 – the initial Homepump premarket notification.
- K944692 – added low flow rates for chemotherapy and pain management.
- K984502 – added intraoperative and nerve block (perineural) routes of administration.
- K991513 – added KVO indications and the optional regulator component.
- K992072 – added bolus option.

1.1.3 No changes will be made to the indications for use, sterilization, fundamental scientific technology, packaging, labeling (except for clarification) or pump.

1.1.4 Common Name: Infusion Pump

1.1.5 Classification Name: Pump, Infusion

1.1.6 Product Code: MEB

1.1.7 Device Classification: Class II, 880.5725

1.1.8 Medical Specialty: General Hospital

2.0 PHYSICAL SPECIFICATIONS AND DESCRIPTONS

2.1 Description of Device

The Homepump consists of an elastomeric pressure source with an integrated administration line. This premarket notification proposes a new component, i.e. the Variable Flow Rate component. No other change will be made to the Homepump.

2.2 The Homepump

See Appendix B for drawings.

2.2.1 The Homepump is an elastomeric infusion pump with an integrated administration set. Fill volumes range from (b) (4) (b) (4)

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

2.2.3 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.

2.2.4 The incorporation of (b) (4) [redacted] combined with the elastomeric pressure source produces the desired flow rate. The administration line may incorporate any of the following optional components:

2.2.4.1 Bolus, filter, variable flow rate and Y-adapter.

Note: All these features with the exception of the variable flow component have been cleared in previous 510(k)s.

2.2.5 The Variable Flow Component:

2.2.5.1 This component has seven flow rates which can be selected from a dial. The dial is labeled with each flow rate and a "key" is used to rotate the dial from position to position. As a flow rate is dialed in, a tactile click can be felt. After the healthcare provider has selected the flow rate, the key may be removed and the dial cover is closed and tied off to prevent inadvertent changes to the flow rate.

See section **3.0** for model configurations.

2.2.5.2 The device contains three microbore tubings. As the dial is turned, tubings are pinched off (closed) and on (opened) which varies the flow rate. For example, model 1 contains three microbore tubings of flow rates 0.5, 1 and 2 ml/hr. As the dial is moved from one labeled flow rate to the next the following occurs:

(b) (4) [redacted]

Thus the OFF position starts with all (b) (4) [redacted] pinched off. When dialed (b) (4) [redacted] tubing is opened and the remaining two tubings remain pinched off which yields (b) [redacted] ml/hr flow rate. When dialed to (b) [redacted] ml/hr, the (b) [redacted] ml/hr tubing is pinched off and the 1.0 ml/hr tubing is opened which results in (b) [redacted] ml/hr flow rate. When dialed to (b) [redacted] ml/hr, both the (b) [redacted] and (b) [redacted] ml/hr tubings are opened and the (b) [redacted] ml/hr tubing remains pinched off which results in a total

of (b) (4) ml/hr flow rate. This continues as the dial is moved from position to position.

2.3 **Flow Control**

2.3.1 The fundamental scientific technology for controlling the flow rate remains the same as the existing (unmodified) Homepump and is identical in technology to the variable flow component cleared under K020251.

2.3.2 Each administration line consists of a fixed diameter flow control tubing or glass orifice.

2.3.3 The flow control tubing or glass orifice is cut to a specific length L. When the pump is filled and pressurized, the flow rates are approximated by Poiseulle's equation:

(b) (4) [redacted]

2.3.4 Where Q is the flow rate, ρ is the pressure drop across the orifice, D is the inside diameter of the flow controlling orifice, μ is the dynamic viscosity of the fluid and L is the length of the orifice. The equation provides an approximation of the actual delivery time.

3.0 NEW MODELS

3.1 (optional) Variable Flow Rate Component

This optional component replaces the standard flow restricting orifice and allows a combination of flow rates to be selected by the healthcare provider. The following models will be available:

3.1.1 Model 1: [redacted] (b) (4) and (b) (4) [redacted] yields:

3.1.1.1 (b) (4) [redacted] ml/hr

3.1.2 Model 2: combination [redacted] (b) (4) ml/hr (b) (4) [redacted] yields:

3.1.2.1 (b) (4) [redacted] ml/hr

3.1.3 Model 3: combination (b) (4) [redacted] ml/hr (b) (4) [redacted] yields:

3.1.3.1 (b) (4) [redacted]

4.0 COMPONENTS AND MATERIALS

Note: No changes in materials will be made to the Homepump. All fluid path materials in the Homepump are in compliance with ISO 10993 prior to market distribution.

The Homepump is disposable and single use only.

5.0 OPERATIONAL SPECIFICATIONS AND DESCRIPTIONS

5.1 **Standard Operating Conditions:**

Priming/Residual Volume: (b) (4) [redacted]
Operating Temperature:
Test Solution:
Operating Pressure:
Accuracy: (b) (4) [redacted]

5.2 **Power Requirements:** The Homepump is a mechanical device that utilizes the strain energy of the elastomeric membranes which are forced to expand when the pump is filled. No additional external power source is required to operate.

5.3 **Safety/Alarm Functions**

5.3.1 The Homepump provides fixed flow and as such is not subject to fluid runaway conditions similar to that of some electronic pumps.

5.3.2 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.

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

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

6.0 BIOCOMPATIBILITY SPECIFICATIONS

6.1 Biocompatibility testing is in conformance with ISO 10993 Part 1 for all fluid path components based on intended application of the device prior to market distribution.

7.0 CHEMICAL AND DRUG SPECIFICATIONS

7.1 Compatibility

7.1.1 There are no specific drugs referenced in the labeling for the Homepump.

7.1.2 The Homepump is intended for general purpose drugs and pain medication.

7.2 Drug Stability

7.2.1 There are no specific drugs referenced in the labeling for the Homepump.

8.0 INDICATIONS FOR USE

8.1 There is no change to indications for use.

8.2 The Homepump is intended for continuous and/or intermittent infusion of medications for general infusion use, including antibiotic delivery, chemotherapy and pain management. Routes of administration include the following: intravenous, intra-arterial, subcutaneous, intramuscular and epidural.

8.3 The Homepump is also intended for continuous and/or intermittent delivery of medication (such as local anesthetics or narcotics) to surgical wound sites and/or close proximity to nerves for preoperative, perioperative and postoperative

regional anesthesia and pain management. Routes of administration may be intraoperative, perineural or percutaneous.

8.4 The Homepump is disposable and single use only.

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

9.0 LABELS AND LABELING

9.1 The only change to the labeling will be for clarification of use of the variable flow rate component.

9.2 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.

9.3 The Homepump Directions for Use labeling:

9.3.1 Provides comprehensive directions for preparation and use for the Homepump.

9.3.2 Describes the routes of administration as it relates to intended use.

9.3.3 Contains warning information.

9.3.4 Contains the prescription statement required under 801.109 (b)(1).

9.3.5 Includes the specifications of the Homepump. The specifications include the priming volume, residual volume, accuracy and operating conditions.

9.4 Identification labels and labeling

9.4.1 I-Flow has developed product identification labeling for the Homepump. Refer to Appendix C for examples.

9.5 Packaging labels

9.5.1 Contains the prescription statement required under 801.109 (b)(1).

10.0 STANDARDS

10.1 There are currently no standards established for elastomeric infusion devices.

11.0 PACKAGING

11.1 There is no change in the packaging. Packaging is in conformance with the standard EN 868-1 (Packaging Materials and Systems for Medical Devices which are to be Sterilized).

11.2 The Homepump is packaged in a sealed Tyvek pouch.

11.3 Packaging is suitable for gamma radiation or ETO sterilization.

11.4 Package aging tests have been conducted on the Tyvek pouch. The results of bacterial dust challenge testing has determined that the Tyvek pouches used to package the disposable Homepump maintain sterility up to five years.

12.0 STERILIZATION

12.1 There is no change in the sterilization methods.

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

12.3 Sterilization validation methodology is by ANSI/AAMI ST32-1991 / EN552 Method 1 for gamma radiation.

12.3.1 The gamma radiation dose validated for this product is (b) (4) [redacted] (b) (4) [redacted].

12.4 Sterilization validation methodology is by ANSI/AAMI/ISO 11135-1994 / EN550 for ETO gas sterilization.

12.4.1 For ETO sterilized product, the maximum levels of gas residuals for ethylene oxide, ethylene chlorohydrin and ethylene glycol are consistent with the FDA proposed rule, 43 FR 2782 (June 23, 1978).

12.4.2 The (b) (4) [redacted] (b) (4) [redacted].

12.5 The sterile product under review here will have a sterilization assurance level (SAL) of 10^{-6}. Sterility testing is by spore strip for ETO. Under AAMI Method 1 for Gamma sterilized product, no sterility test is required.

12.6 The Homepump is labeled pyrogen free and is tested for pyrogens using either the USP Rabbit Pyrogen Test or LAL test methods.

12.6.1 I-Flow products have been validated for LAL testing.

12.6.2 Either method may be used as necessary.

13.0 COMPARISON TO THE EXISTING (UNMODIFIED) HOMEPUMP

13.1 Intended Use

13.1.1 No change in intended use.

13.2 Fundamental Scientific Technology

13.2.1 No change in technology.

13.2.2 The Homepump is identical to the existing Homepump with the exception of the variable flow component. The variable flow component is identical to the one cleared under K020251.

13.3 Operational Specifications

13.3.1 No change in specification other than temperature calibration.

13.3.2 The operational specifications for the (b) (4) [redacted] same as the existing (unmodified) Homepump except for the (b) (4) [redacted]. The variable flow rate sets are calibrated at (b) (4) [redacted] (unmodified) low flow rate Homepump are calibrated at skin temperature as the orifice is taped to the skin.

13.4 No change in sterilization or packaging.

Appendix A

Title: Risk Assessment for the Variable Flow Rate Component

Doc. No.: DCD1121 Rev.: A

DCN: 5390 Effectivity: 1/2/02

Approval Signature	Date	Approval Signature	Date
Prepared By: Shane Noehre	12/17/2001	(b) (6) [redacted]	12/20/01
(b) (6) [redacted]	12/20/01		1/02/02
	12/28/01		1/21/02

Rev.	Rel. Date	DCN

PAGE 1 OF 5
CONTROL COPY
REV. A
DCD1121

1.0 PURPOSE

1.1 To identify the hazards associated with the (b) (4) [redacted], estimate and evaluate the risks and control the risks.

2.0 SCOPE

2.1 This risk assessment encompasses the Variable Flow Rate Component. A separate risk assessment will be done for the pump.

3.0 REFERENCES

Note: The following references are always at the most current revision level. Document Control can verify the revision status.

3.1 Title 21 CFR Part 820 US FDA GMP Quality System Regulation

3.2 ISO 9001: Quality systems - Model for quality assurance in design, development, production, installation and servicing

3.3 EN 46001: Quality systems - Medical Devices - Particular requirements for the application of EN ISO 9001

3.4 ISO 13485: Quality systems – Medical Devices – Particular requirements for the application of ISO 9001

3.5 Medical Device Directives (MDD)

3.6 EN ISO 14971 – Medical Devices: Application of Risk Management to Medical Devices

3.7 SOP305 – Risk Management Procedure

4.0 RISK ANALYSIS

4.1 Conducted By:

4.1.1 (b) (4) [redacted]

4.2 Device Description

4.2.1 This component has seven flow rates which can be selected from a dial. The dial is labeled with each flow rate and a "key" is used to rotate the dial from position to position. As a flow rate is dialed in, a tactile click can be felt. After the healthcare provider has selected the flow rate, the key may be

removed and the dial cover is closed and tied off to prevent inadvertent changes to the flow rate.

4.2.2 The pump along with the flow control tubing in the Variable Flow Rate Component provide the mechanical power to regulate flow in the set.

4.2.3 Each I-Flow administration set usually contains an air eliminating and particulate filter and pinch clamp. Additional components may be found on specific models.

4.3 Intended Use

4.3.1 The Variable Flow Rate Component will be an optional flow rate component for use with I-Flow ambulatory infusion pumps (such as the Paragon or elastomeric pumps). The indications for use will be the same as the pump but the healthcare provider will have the option to set or change the flow rate as desired.

5.0 RISK EVALUATION

5.1 See Table 1 for FMEA analysis. Risk Estimation was accomplished by the following:

5.1.1 Qualitative measures: Expert opinion and past experience.

5.1.2 Quantitative measures: Review of complaint/failure history, design verification/validation.

5.2 The greatest risk to the patient is a compromise in sterility or inaccurate or fast flow delivery.

5.2.1 The (b) (4) [redacted] has been evaluated and can't be further reduced. The probabilities of a breach in sterility are low and warnings are provided in the DFU not to use the product if the package has been damaged, if any of the protector caps are missing, to use aseptic technique and for single use only.

5.2.2 The (b) (4) [redacted] (b) (4) [redacted] These risks have undergone the Risk Control measures outlined in section 6.0.

5.3 No further risk control measures are required.

6.0 RISK CONTROL

6.1 The probability for either the finger plate or cam to be out of specification was found to be too high (P3) which resulted in an unacceptable risk (P3 x S4 = R12). The following risk control measures will be implemented to reduce the probability to P2 which yields a risk as low as reasonably possible (ALARP):

6.1.1 Incoming inspection shall inspect all critical dimensions per the drawings;

6.1.2 Fixtures and inprocess inspection shall ensure that components are within specification and not damaged;

6.1.3 Flow rate, leak and occlusion testing shall ensure proper functioning of the device.

6.2 The probability for patient tampering was found to be (b) (4) [redacted] which resulted in an unacceptable risk (b) (4) [redacted]). The following risk control measures have been implemented to reduce the probability to P2 which yields a risk as low as reasonably possible (ALARP):

PAGE 2 OF 5
CONTROL COPY
REV. A
DCD1121

6.2.1 A removable key will be used to dial flow rates;

6.2.2 In addition, a lockable cover hinders patient tampering.

6.3 The following Risk Control measures have been implemented throughout the design and development process per SOP420:

6.3.1 Inherent Safety by Design

6.3.1.1 (b) (4) [redacted]

6.3.1.2 (b) (4) [redacted]

6.3.2 Protective measures in device or in the manufacturing process

6.3.2.1 Incoming inspection and inprocess inspection procedures exist to ensure the device meets specification.

6.3.3 Information for Safety

6.3.3.1 (b) (4) [redacted]

6.4 Verification and Validation reports in the Device Master Record and/or Technical File shall document the effectiveness of risk control.

7.0 RISK MANAGEMENT REPORT

7.1 The product design has been reviewed and found to be acceptable in safety and efficacy. (b) (4) [redacted] No special conditions are found to be required for maintaining safety and efficacy.

PAGE 3 OF 5
CONTROL COPY
REV. A
DCD1121

Table 1 - Failure Mode and Effect Analysis (FMEA)

POTENTIAL HAZARDS	POTENTIAL FAILURES/CAUSES	POTENTIAL EFFECTS	PROBABILITY	SEVERITY	RISK ESTIMATION	COUNTER MEASURE
[redacted]						

(b) (4)

Table 1 - Failure Mod and Effect Analysis (FMEA) (cont.)

POTENTIAL HAZARDS	POTENTIAL FAILURES/CAUSES	POTENTIAL EFFECTS	PROBABILITY	SEVERITY	RISK ESTIMATION	COUNTER MEASURE
[redacted]						

(b) (4)

Appendix B

(b) (4)

4 3 2 1

Revisions

Zone	Rev.	Description	Date	Chg. by	Ck. by
	A	PRODUCTION RELEASE PER DCO 4968	4/23/01	CP	

D C B A

[redacted]

(b) (4)

DWG NO. 2001483 SH. 1 REV A

42

Appendix C

I·FLOW®

REF H005-035

(1) Homepump® *Select-A-Flow*™

Variable Rate Controller

300 ml Vol, 0.5 ml/hr - 3.5 ml/hr

CAUTION: Device is initially set at maximum flow rate. Adjust as necessary.

STERILE R

LOT

SEE DIRECTIONS FOR USE. SINGLE USE ONLY.
CAUTION: FEDERAL LAW (U.S.A.) RESTRICTS THIS DEVICE TO SALE BY OR ON THE ORDER OF A PHYSICIAN.

Manufactured by:
I-Flow Corporation
Lake Forest, CA 92630 U.S.A.
www.i-flowcorp.com
Assembled in Mexico

CE 0123

European Representative:
MPS Medical Product Service GmbH
Borngasse 20, 35619 Braunfels, Germany

U S and Foreign Patents Pending

44

I·FLOW®

REF H010-070

(1) Homepump® *Select-A-Flow*™

Variable Rate Controller

300 ml Vol, 1.0 ml/hr – 7.0 ml/hr

CAUTION: Device is initially set at maximum flow rate. Adjust as necessary.

STERILE R LOT

SEE DIRECTIONS FOR USE. SINGLE USE ONLY.
CAUTION: FEDERAL LAW (U.S.A.) RESTRICTS THIS DEVICE TO SALE BY OR ON THE ORDER OF A PHYSICIAN.

Manufactured by:
I-Flow Corporation
Lake Forest, CA 92630 U.S.A.
www.i-flowcorp.com
Assembled in Mexico

CE 0123

European Representative:
MPS Medical Product Service GmbH
Borngasse 20, 35619 Braunfels, Germany

U S and Foreign Patents Pending

45

I-FLOW®

REF H020-140

(1) Homepump® *Select-A-Flow*™

Variable Rate Controller

300 ml Vol, 2.0 ml/hr – 14.0 ml/hr

CAUTION: Device is initially set at maximum flow rate. Adjust as necessary.

STERILE R

LOT

SEE DIRECTIONS FOR USE. SINGLE USE ONLY.
CAUTION: FEDERAL LAW (U.S.A.) RESTRICTS THIS DEVICE TO SALE BY OR ON THE ORDER OF A PHYSICIAN.

Manufactured by:
I-Flow Corporation
Lake Forest, CA 92630 U.S.A.
www.i-flowcorp.com
Assembled in Mexico

CE 0123

European Representative:
MPS Medical Product Service GmbH
Borngasse 20, 35619 Braunfels, Germany

U.S. and Foreign Patents Pending

46

Models: H005-035, H010-070, H020-140

Homepump® Infusion System with

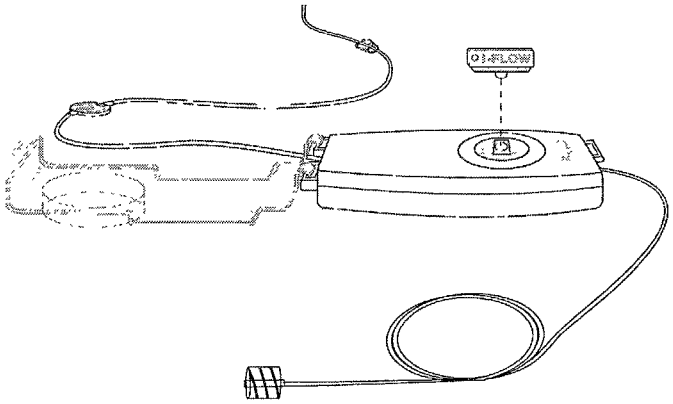
Select-A-Flow™

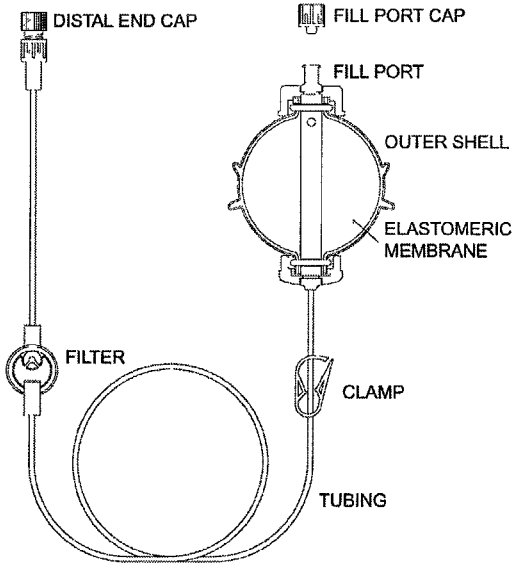
Variable Rate Controller

Manufactured by:
I-Flow Corporation
Lake Forest, CA 92630
U.S.A.

CE 0123

European Representative:
MPS Medical Product Service GmbH
Borngasse 20, 35619 Braunfels
Germany





Homepump® Infusion System with *Select-A-Flow*™ Variable Rate Controller

DIRECTIONS FOR USE

INDICATIONS FOR USE

The *Select-A-Flow* Administration Set incorporates a controller that allows the user to adjust the infusion rate by turning the rate-changing key on the device. The flow rate is within a predetermined range and is designated on each device.

The *Select-A-Flow* Administration Set is intended for use with the *Homepump* Infusion Pump. The *Homepump* is intended for delivery of medications for general infusion use, including chemotherapy and pain management. Routes of administration include intravenous, intra-arterial, perineural, subcutaneous, percutaneous, intraoperative, intramuscular and epidural.

CAUTIONS

1. Do not use if the package has been opened or is damaged or if either protector cap is not in place.
2. Device is initially set at maximum flow rate. Adjust as necessary.
3. If the *Select-A-Flow* Administration Set is to be used for epidural drug administration, it should be labeled to differentiate from other routes of administration. Do not use a Y-adapter for epidural delivery. When using the *Select-A-Flow* Administration Set for epidural drug delivery, make certain only drugs recommended for this route of administration are used.
4. Do not resterilize the *Select-A-Flow* Administration Set set. Administration sets are intended for single use only. The fluid pathway is sterile and nonpyrogenic. It is recommended that the administration set be changed in accordance with CDC guidelines or institutional policies.

5. **CAUTION:** Federal (U.S.A.) law restricts this device to sale by or on the order of a physician.

CONTRAINDICATION

This product is not intended for the delivery of blood, blood products, lipids or fat emulsions.

FILLING THE HOMEPUMP

CAUTION: Use Aseptic Technique

1. Remove the Homepump with the attached *Select-A-Flow* from its package.
2. Remove the white tape from around the pump and remove the cap from the fil port.
3. The Homepump can be filled with a syringe or similar device. After all air has been removed from the filling device, attach securely to the fill port.
4. Close the clamp and fill the Homepump with no more than the recommended maximum fill volume (refer to the table on the other side of this sheet).
5. Remove filling device from the fill port.
6. Securely replace fill port cap. Ensure that the distal end cap is tightened securely.
7. Label with the appropriate pharmaceutical and patient information.. Labels may be wrapped around the *Select-A-Flow* Administration Set tubing.

PRIMING THE VARIABLE RATE ADMINISTRATION SET

Use Aseptic Technique

1. Allow Homepump to warm to room temperature before using. (refer to the table on the other side of this sheet for guidelines).
2. Verify that the clamp on the tubing is closed.
3. Open the plastic cover and ensure the dial on the face of the device is at the highest flow rate setting. Make sure you feel or hear the dial "click" into place and the selected flow rate is aligned below the ml/hr mark on the *Select-A-Flow* Variable Rate Controller.
2. Open the clamp and remove the cap from the luer lock at the end of the set.
3. Medication will flow toward the end of the set.
4. When all air has been removed from the *Select-A-Flow* Administration Set and fluid is observed at the end of the luer lock, turn the dial to the, Ø, off position and replace the cap on the end of the *Select-A-Flow* Administration Set.

CAUTION: Make sure the dial is in the, Ø, off position or the clamp is closed.

STARTING THE INFUSION

- Do not use while showering, bathing, or swimming.

1. Connect the *Select-A-Flow* Administration Set to the patient's catheter. Make sure the connection is secure.
2. Select the appropriate flow rate by turning the dial on the *Select-A-Flow* Variable Rate Controller until the dial clicks into place, and the flow rate setting is aligned with the ml/hr mark on the face of the *Select-A-Flow* Variable Rate Controller.

CAUTION: Ensure proper flow rate is dialed.

WARNING: To discourage tampering, remove the rate-changing key from the dial by pulling the key straight out. Put the key in a safe place for later use, e.g., attached to a key ring.

Close the cover over the *Select-A-Flow* Variable Rate Controller. For increased tamper resistance, the cover may be locked to the *Select-A-Flow* Variable Rate Controller using a standard tie wrap.

Note: If desired, the cover may also be removed from the *Select-A-Flow* Variable Rate Controller by fully opening the cover and then pulling straight up on the plastic feet at the bottom of the cover.

CHANGING THE FLOW RATE DURING AN INFUSION

1. Insert the rate-changing key into the dial.
2. Turn the dial until the new flow rate is selected. Make sure you hear the dial "click" into place and the selected flow rate is aligned below the ml/hr mark on the *Select-A-Flow* Variable Rate Controller.
3. Remove the key from the dial and put in a safe place for later use.

THE END OF THE INFUSION

When the elastomeric membrane is no longer extended, infusion is complete. Disconnect and dispose of the Homepump as instructed by your healthcare provider.

IMPORTANT

1. This product uses DEHP-plasticized PVC. Certain solutions may be incompatible with the PVC material used in the *Select-A-Flow* Administration Set. Consult the drug package insert and other available sources of information for a more through understanding of possible incompatibility problems.

2. Only administration sets manufactured by I-Flow Corporation are authorized for use with this product. I-Flow Corporation accepts no responsibility for performance, or the liability for damages, caused by misuse of this product when used with unauthorized administration sets.

THE *SELECT-A-FLOW* ADMINISTRATION SET

Flow Rates: Three different color-coded *Select-A-Flow* Administration Sets are available with the following flow rate range:

- White - 2, 4, 6, 8, 10, 12, 14 ml/hr
- Green - 1, 2, 3, 4, 5, 6, 7 ml/hr
- Blue - 0.5, 1, 1.5, 2, 2.5, 3, 3.5 ml/hr

Delivery Accuracy: Flow rate accuracy is ± 15% at a 95% confidence interval.

Residual Volume: 9 ml or less

CAUTIONS

Actual infusion times may vary from the specified range due to:

- viscosity and/or drug concentration
- temperatures above or below the operating conditions
- the positioning of the Homepump above or below the infusion site.

The *Select-A-Flow* Administration Set has been calibrated using Normal Saline (NS) as the diluent and room temperature (21°C, 72°F) as the operating environment. When using NS and room temperature the Homepump will flow at the specified nominal rate.

The use of other diluent or operating temperatures other than the above will affect the nominal flow rate. For example, if 5% dextrose (D5W) is used as the final diluent, the Homepump will flow at 10% below the nominal rate due to higher solution viscosity.

Outside the USA or for I-Flow Corporation:

Within the USA:

800.448.3569

or:

949.206.2700

www.i-flowcorp.com

® Homepump is a registered trademark of I-Flow Corporation registered with the U.S. Patent Office.

U.S. and Foreign Patents pending.

Appendix D

Return to Search

Device	PUMP, INFUSION, ELASTOMERIC
Medical Specialty	General Hospital
Product Code	MEB
Device Class	2
510(k) Exempt?	No
Regulation Number	880.5725
Third Party Review	Eligible for *Mutual Recognition Agreement Program* Eligible for *Accredited Persons Program* Accredited Persons and Third Party Program Information Mutual Recognition Agreement Program Information

Accredited Persons

- BRITISH STANDARDS INSTITUTION
- CALIFORNIA DEPARTMENT OF HEALTH SERVICES
- CENTER FOR MEASUREMENT STANDARDS OF INDUSTRIAL
- CITECH
- ENTELA, INC.
- INTERTEK TESTING SERVICES
- N.V. KEMA
- TUV PRODUCT SERVICE, INC.
- TUV RHEINLAND OF NORTH AMERICA, INC.
- UNDERWRITERS LABORATORIES, INC.

(Database Updated February 7, 2002)
Accessibility

Return to Search

Device Classification Name	STERILANT, MEDICAL DEVICES
Regulation Number	880.6885
510(k) Number	K932740
Device Name	HOMEPUMP NSF
Applicant	BLOCK MEDICAL, INC. 5957 LANDAU COURT CARLSBAD, CA 92008
Contact	IAN KENNEDY
Product Code	MED
Date Received	06/08/1993
Decision Date	10/06/1993
Decision	SUBSTANTIALLY EQUIVALENT (SE)
Classification Advisory Committee	General Hospital
Review Advisory Committee	General Hospital
Statement/Summary/Purged Status	Summary/purged 510(k)
Type	Traditional
Reviewed by Third Party	No

(Database Updated February 7, 2002)
Accessibility

Return to Search

Device Classification Name	SET, ADMINISTRATION, INTRAVASCULAR
Regulation Number	880.5440
510(k) Number	K944692
Device Name	C-SERIES HOMEPUMP
Applicant	BLOCK MEDICAL, INC. 5957 LANDAU COURT CARLSBAD, CA 92008
Contact	ROBERT J BARD
Product Code	FPA
Date Received	09/23/1994
Decision Date	05/02/1995
Decision	SUBSTANTIALLY EQUIVALENT (SE)
Classification Advisory Committee	General Hospital
Review Advisory Committee	General Hospital
Statement/Summary/Purged Status	Summary only
Type	Traditional
Reviewed by Third Party	No

(Database Updated February 7, 2002)
Accessibility

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.

56

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

57

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)

(b) (6) [redacted] 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)

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.

59

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

K991513

I-FLOW CORPORATION
20202 Windrow Drive
Lake Forest, CA 92630
(800) 448-3569 (949) 206-2700
Fax (949) 206-2600

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.

(b) (6) [redacted]

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

(Optional Format 1-2-96)

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP 15 1999

Mr. Stan Fry
Vice President Regulatory and Legal Affairs
I-Flow Corporation
20202 Window Drive
Lake Forest, California 92630

Re: K992072
Trade Name: Bolus Accessory Set
Regulatory Class: II
Product Code: FPA
Dated: June 17, 1999
Received: June 19, 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

62

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

63

I-FLOW CORPORATION
20202 Windrow Drive
Lake Forest, CA 92630
(800) 448-3569 (949) 206-2700
Fax (949) 206-2600

510(k) Number (if known): _____

Device Name: Bolus Accessory Set

Indications for Use:

1. The Bolus Accessory Set, in combination with a positive pressure, continuous flow infusion pump, is intended to deliver fixed boluses of medication upon demand by the patient or healthcare provider. Routes of administration include intravenous, epidural, intramuscular, subcutaneous, intra-operative [redacted] and percutaneous.

(b) (6) [redacted]

(Division Sign-Off)
Division of Dental, Infection Control,
and General Hospital Devices
510(k) Number K992072

(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)

SPECIAL 510(k): D vice Modification
ODE R vi w M morandum

To: THE FILE **RE:** DOCUMENT NUMBER K020660
I-Flow Variable Flow Elastomeric Pump

This 510(k) submission contains information/data on modifications made to the SUBMITTER'S own Class II, Class III or Class I devices requiring 510(k). The following items are present and acceptable (delete/add items as necessary):

1. The name and 510(k) number of the SUBMITTER'S previously cleared device. (For a preamendments device, a statement to this effect has been provided.)
2. Submitter's statement that the **INDICATION/INTENDED USE** of the modified device as described in its labeling **HAS NOT CHANGED** along with the proposed labeling which includes instructions for use, package labeling, and, if available, advertisements or promotional materials.
3. A description of the device **MODIFICATION(S),** including clearly labeled diagrams, engineering drawings, photographs, user's and/or service manuals in sufficient detail to demonstrate that the **FUNDAMENTAL SCIENTIFIC TECHNOLOGY** of the modified device **has not changed**.

   This change was for the provision of an optional variable flow rate component (recently cleared under K020251) for I-Flow's Homepump Eclipse, K932740; Homepump C-Series, K944692; Nerve Block Infusion Kit, K984502; C-Series and KVO, K991513; and Homepump Bolus, K992072. This optional variable flow component will replace the standard flow-restricting orifice. It will be available in three models: Model 1, with variable flow rates between 0.5 to 3.5 ml/hr.; Model 2, with variable flow rates between 1 and 7 ml/hr; and Model 3, with variable flow rates between 2 and 14 ml/hr.
4. **Comparison Information** (similarities and differences) to applicant's legally marketed predicate device including, labeling, intended use, physical characteristics, and operational specifications. The optional variable flow rate component is identical to the one cleared under K020251, as stated above. The calibration of the flow control tubings for the Homepump pressure source vs the Paragon pressure source is the only difference noted.
5. A **Design Control Activities Summary** which includes:
   a) Identification of Risk Analysis method(s) used to assess the impact of the modification on the device and its components, and the results of the analysis
   b) Based on the Risk Analysis, an identification of the verification and/or validation activities required, including methods or tests used and acceptance criteria to be applied
   c) A declaration of conformity with design controls. The declaration of conformity should include:
      i) A statement signed by the individual responsible, that, as required by the risk analysis, all verification and validation activities were performed by the designated individual(s) and the results demonstrated that the predetermined acceptance criteria were met, and
      ii) A statement signed by the individual responsible, that the manufacturing facility is in conformance with design control procedure requirements as specified in 21 CFR 820.30 and the records are available for review.
6. A **Truthful and Accurate Statement**, a **510(k) Summary or Statement** and the **Indications for Use Enclosure (and Class III Summary for Class III devices).**

The labeling for this modified subject device has been reviewed to verify that the indication/intended use for the device is unaffected by the modification. In addition, the submitter's description of the particular modification(s) and the comparative information between the modified and unmodified devices demonstrate that the fundamental scientific technology has not changed. The submitter has provided the design control information as specified in The New 510(k) Paradigm and on this basis, I recommend the device be determined substantially equivalent to the previously cleared (or their preamendment) device.

Irene Naveau 3/20/02
(Reviewer's Signature) (Date)

PC
3/20/02

6

Comments

The labeling refers to the Homepump as " Select-A-Flow™ Variable Rate Controller."

revised: 3/27/98

SCREENING CHECKLIST
FOR ALL PREMARKET NOTIFICATION [510(k)] SUBMISSIONS

510(k) Number: K020660

The cover letter clearly identifies the type of 510(k) submission as (Check the appropriate box):

☑ Special 510(k) - Do Sections 1 and 2

☐ Abbreviated 510(k) - Do Sections 1, 3 and 4

☐ Traditional 510(k) or no identification provided - Do Sections 1 and 4

Section 1: Required Elements for All Types of 510(k) submissions:

	Present	Inadequate or Missing
Cover letter, containing the elements listed on page 3-2 of the Premarket Notification [510)] Manual.	✓	
Table of Contents.	✓	
Truthful and Accurate Statement.	✓	
Device's Trade Name, Device's Classification Name and Establishment Registration Number.	✓	
Device Classification Regulation Number and Regulatory Status (Class I, Class II, Class III or Unclassified).	✓	
Proposed Labeling including the material listed on page 3-4 of the Premarket Notification [510)] Manual.	✓	
Statement of Indications for Use that is on a separate page in the premarket submission.	✓	
Substantial Equivalence Comparison, including comparisons of the new device with the predicate in areas that are listed on page 3-4 of the Premarket Notification [510)] Manual.	✓	
510(k) Summary or 510(k) Statement.	✓	
Description of the device (or modification of the device) including diagrams, engineering drawings, photographs or service manuals.	✓	
Identification of legally marketed predicate device. *		
Compliance with performance standards. * [See Section 514 of the Act and 21 CFR 807.87 (d).]		
Class III Certification and Summary. **		
Financial Certification or Disclosure Statement for 510(k) notifications with a clinical study. * [See 21 CFR 807.87 (i)]		
510(k) Kit Certification ***		

* - May not be applicable for Special 510(k)s.
** - Required for Class III devices, only.
*** - See pages 3-12 and 3-13 in the Premarket Notification [510)] Manual and the Convenience Kits Interim Regulatory Guidance.

11

Section 2: Required Elements for a SPECIAL 510(k) submission:

	Present	Inadequate or Missing
Name and 510(k) number of the sponsor's own, unmodified predicate device.		
A description of the modified device and a comparison to the sponsor's predicate device.		
A statement that the intended use(s) and indications of the modified device, as described in its labeling, are the same as the intended uses and indications for the sponsor's unmodified predicate device.		
A statement that the modification has not altered the fundamental technology of the sponsor's predicate device.		
A Design Control Activities Summary that includes the following elements (a-e):		
a. Identification of Risk Analysis method(s) used to assess the impact of the modification on the device and its components, and the results of the analysis.		
b. Based on the Risk Analysis, an identification of the required verification and validation activities, including the methods or tests used and the acceptance criteria to be applied.		
c. A Declaration of Conformity with design controls that includes the following statements:		
A statement that, as required by the risk analysis, all verification and validation activities were performed by the designated individual(s) and the results of the activities demonstrated that the predetermined acceptance criteria were met. This statement is signed by the individual responsible for those particular activities.		
A statement that the manufacturing facility is in conformance with the design control procedure requirements as specified in 21 CFR 820.30 and the records are available for review. This statement is signed by the individual responsible for those particular activities.		

12

Section 3: Required Elements for an ABBREVIATED 510(k)* submission:

	Present	Inadequate or Missing
For a submission, which relies on a guidance document and/or special control(s), a summary report that describes how the guidance and/or special control(s) was used to address the risks associated with the particular device type. (If a manufacturer elects to use an alternate approach to address a particular risk, sufficient detail should be provided to justify that approach.)		
For a submission, which relies on a recognized standard, a declaration of conformity [For a listing of the required elements of a declaration of conformity, SEE **Required Elements for a Declaration of Conformity to a Recognized Standard,** which is posted with the 510(k) boilers on the **H drive.**]		
For a submission, which relies on a recognized standard without a declaration of conformity, a statement that the manufacturer intends to conform to a recognized standard and that supporting data will be available before marketing the device.		
For a submission, which relies on a non-recognized standard that has been historically accepted by FDA, a statement that the manufacturer intends to conform to a recognized standard and that supporting data will be available before marketing the device.		
For a submission, which relies on a non-recognized standard that has not been historically accepted by FDA, a statement that the manufacturer intends to conform to a recognized standard and that supporting data will be available before marketing the device and any additional information requested by the reviewer in order to determine substantial equivalence.		
Any additional information, which is not covered by the guidance document, special control, recognized standard and/or non-recognized standard, in order to determine substantial equivalence.		

* - When completing the review of an abbreviated 510(k), please fill out an Abbreviated Standards Data Form (located on the H drive) and list all the guidance documents, special controls, recognized standards and/or non-recognized standards, which were noted by the sponsor.

13

Section 4: Additional Requirements for ABBREVIATED and TRADITIONAL 510(k) submissions (If Applicable):

	Present	Inadequate or Missing
a) Biocompatibility data for all patient-contacting materials, OR certification of identical material/formulation:		
b) Sterilization and expiration dating information:		
i) sterilization process		
ii) validation method of sterilization process		
iii) SAL		
iv) packaging		
v) specify pyrogen free		
vi) ETO residues		
vii) radiation dose		
c) Software Documentation:		

Items with checks in the "Present but Deficient" column require additional information from the sponsor. Items with checks in the " Missing" column must be submitted before substantive review of the document.

Passed Screening ✓ Yes No
Reviewer: (b) (6) [redacted]
Concurrence by Review Branch:

Date: MAR - 4 2002

The deficiencies identified above represent the issues that we believe need to be resolved before our review of your 510(k) submission can be successfully completed. In developing the deficiencies, we carefully considered the statutory criteria as defined in Section 513(i) of the Federal Food, Drug, and Cosmetic Act for determining substantial equivalence of your device. We also considered the burden that may be incurred in your attempt to respond to the deficiencies. We believe that we have considered the least burdensome approach to resolving these issues. If, however, you believe that information is being requested that is not relevant to the regulatory decision or that there is a less burdensome way to resolve the issues, you should follow the procedures outlined in the "A Suggested Approach to Resolving Least Burdensome Issues" document. It is available on our Center web page at: http://www.fda.gov/cdrh/modact/leastburdensome.html

14

Internal Administrative Form

	YES	NO
1. Did the firm request expedited review?		✓
2. Did we grant expedited review?		✓
3. Have you verified that the Document is labeled Class III for GMP purposes?		✓
4. If, not, has POS been notified?		✓
5. Is the product a device?	✓	✓
6. Is the device exempt from 510(k) by regulation or policy?		✓
7. Is the device subject to review by CDRH?	✓	
8. Are you aware that this device has been the subject of a previous NSE decision?		✓
9. If yes, does this new 510(k) address the NSE issue(s), (e.g., performance data)?		✓
10. Are you aware of the submitter being the subject of an integrity investigation?		✓
11. If, yes, consult the ODE Integrity Officer.		
12. Has the ODE Integrity Officer given permission to proceed with the review? (Blue Book Memo #I91-2 and Federal Register 90N0332, September 10, 1991.		✓

15

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Food and Drug Administration

Memorandum

Date: 3/20/02

From: Reviewer(s) - Name(s) Irene Nareau

Subject: 510(k) Number K020660

To: The Record - It is my recommendation that the subject 510(k) Notification:

- ☐ Refused to accept.
- ☐ Requires additional information (other than refuse to accept).
- ☒ Is substantially equivalent to marketed devices.
- ☐ NOT substantially equivalent to marketed devices.
  - De Novo Classification Candidate? ☐ YES ☐ NO
- ☐ Other (e.g., exempt by regulation, not a device, duplicate, etc.)

Is this device subject to Postmarket Surveillance?	☐ YES	☒ NO
Is this device subject to the Tracking Regulation?	☐ YES	☒ NO
Was clinical data necessary to support the review of this 510(k)?	☐ YES	☒ NO
Is this a prescription device?	☒ YES	☐ NO
Was this 510(k) reviewed by a Third Party?	☐ YES	☒ NO
Special 510(k)?	☒ YES	☐ NO
Abbreviated 510(k)? Please fill out form on H Drive 510k/boilers	☐ YES	☒ NO

This 510(k) contains:

Truthful and Accurate Statement ☐ Requested ☒ Enclosed
(required for originals received 3-14-95 and after)

☒ A 510(k) summary OR ☐ A 510(k) statement

☐ The required certification and summary for class III devices

☒ The indication for use form (required for originals received 1-1-96 and after)

Material of Biological Origin ☐ YES ☐ NO

The submitter requests under 21 CFR 807.95 (doesn't apply for SEs):

☐ No Confidentiality ☐ Confidentiality for 90 days ☐ Continued Confidentiality exceeding 90 days

Predicate Product Code with class: 80/MEB/II/880.5725

Additional Product Code(s) with panel (optional):

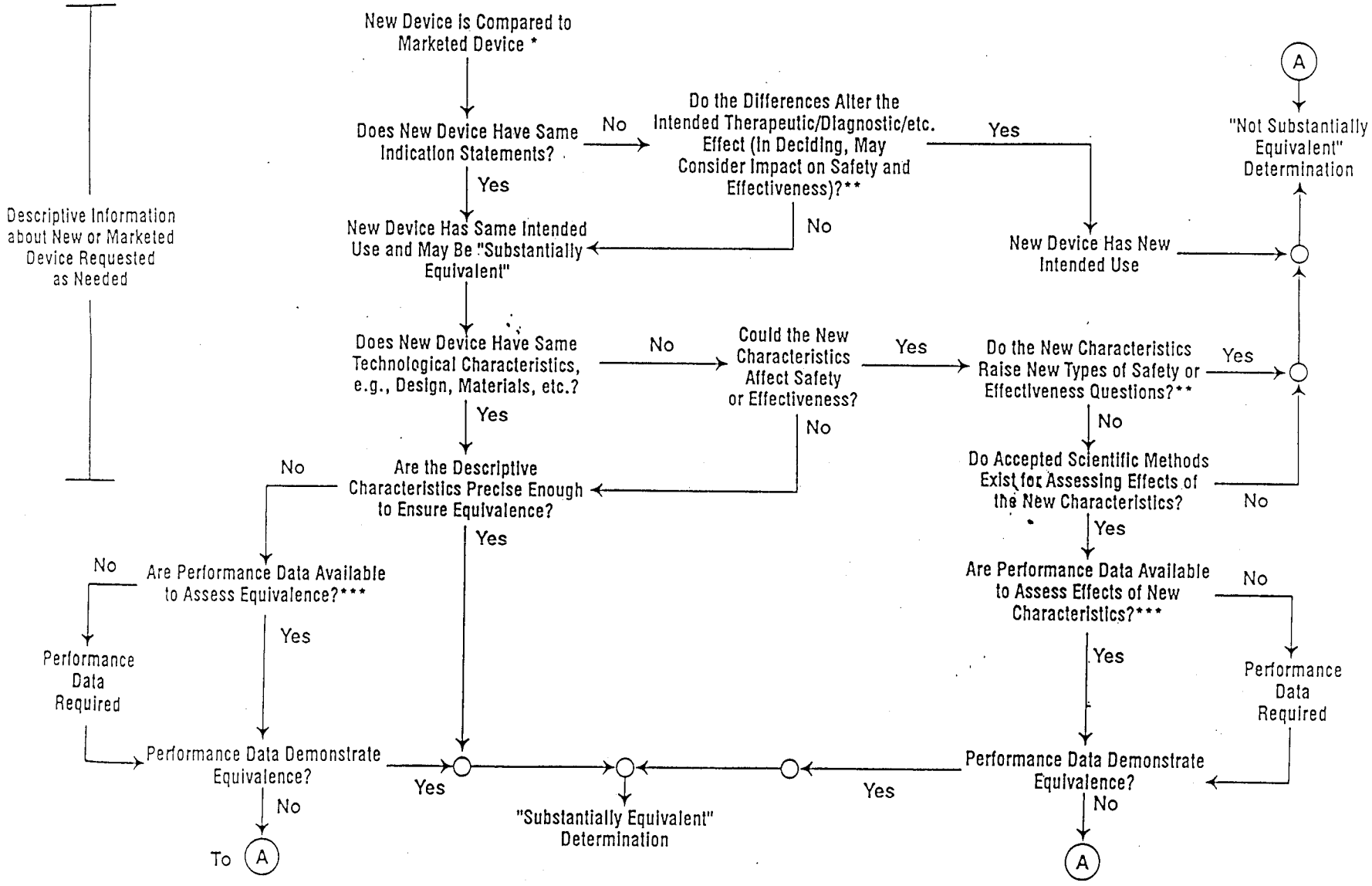
Review: (b) (6) [redacted] (Branch Chief) GHDB (Branch Code) 3/20/02 (Date)

Final Review: Susan Runner for (Division Director) 3/20/02 (Date)

Revised:8/17//99

4

510(k) "Substantial Equivalence" Decision-Making Process (Detailed)



* 510(k) Submissions Compare New Devices to Marketed Devices. FDA Requests Additional Information if the Relationship Between Marketed and "Predicate" (Pre-Amendments or Reclassified Post-Amendments) Devices is Unclear.

** This Decision is Normally Based on Descriptive Information Alone, But Limited Testing Information is Sometimes Required.

*** Data May Be in the 510(k), Other 510(k)s, The Center's Classification Files, or the Literature.