



USER: COLMES, JERI R (jrc)

FOLDER: K023883 - 73 pages (FOI:03008872)

COMPANY: I-FLOW CORP. (IFLOW)

PRODUCT: PUMP, INFUSION, ELASTOMERIC (MEB)

SUMMARY: Product: HOMEPUMP, ECLIPSE, C-SERIES,
PAINBUSTER, C-BLOC, ON-Q, EASYPUMP,
KVO

DATE REQUESTED: Tue Sep 19 24:00:00 2006

DATE PRINTED: Fri Dec 08 10:12:11 2006

Note: Releasable Version

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K023883

SPECIAL 510(K) - SUMMARY OF SAFETY AND EFFECTIVENESS

December 18, 2002

DEC 20 2002

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

Contact: Shane Noehre
Director, 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 (K020660)

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 labeling change to the existing device submitted under K020660 for the variable flow rate component.

Technology Comparison: The Variable Flow Rate Component is identical in design to the one recently cleared under K020660.

Conclusion: The I-Flow Variable Rate Elastomeric Pump was cleared under K020660 on March 20, 2002. It was found to be substantially equivalent to the existing I-Flow Elastomeric Pump and the variable flow rate component cleared under K020251.



DEC 20 2002

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Mr. Shane Noehre
Director, Regulatory Affairs
I-Flow Corporation
20202 Windrow Drive
Lake Forest, California 92630

Re: K023883

Trade/Device Name: I-Flow Variable Rate Elastomeric Pump
Regulation Number: 880.5725
Regulation Name: Infusion Pump
Regulatory Class: II
Product Code: MEB
Dated: November 19, 2002
Received: November 21, 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.

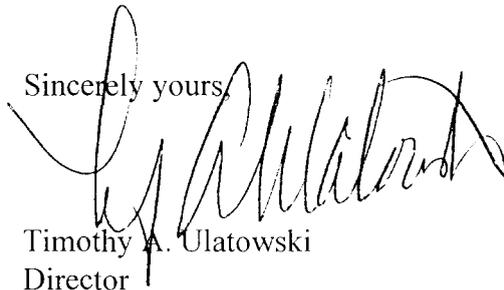
Page 2 – Mr. Noehre

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), 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,



Timothy A. Ulatowski
Director

Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure



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: 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)

Alvin Ciccone

(Division Sign-Off)
Division of Anesthesiology, General Hospital,
Infection Control, Dental Devices

510(k) Number: 1023883



DEC 20 2002

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Mr. Shane Noehre
Director, Regulatory Affairs
I-Flow Corporation
20202 Windrow Drive
Lake Forest, California 92630

Re: K023883
Trade/Device Name: I-Flow Variable Rate Elastomeric Pump
Regulation Number: 880.5725
Regulation Name: Infusion Pump
Regulatory Class: II
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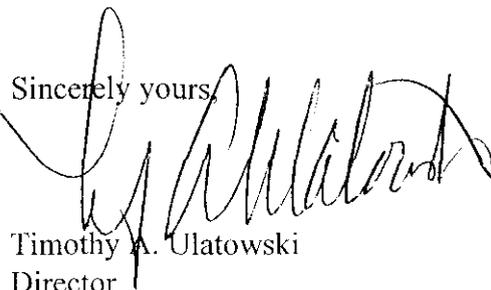
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Page 2 – Mr. Noehre

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Sincerely yours,


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

Enclosure



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: 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.
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(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)

Robert Curcote

(Division Sign-Off)
Division of Anesthesiology, General Hospital,
Infection Control, Dental Devices

510(k) Number: 11023883

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

November 21, 2002

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

510(k) Number: K023883
Received: 21-NOV-2002
Product: HOMEPUMP, ECLIPSE,
C-SERIES,
PAINBUSTER, C-BLOC,
ON-Q, EASYPUMP, KVO

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. Also, please note the new Blue Book Memorandum regarding Fax and E-mail Policy entitled, "Fax and E-Mail Communication with Industry about Premarket Files Under Review. Please refer to this guidance for information on current fax and e-mail practices at www.fda.gov/cdrh/ode/a02-01.html.

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

15023883

Special 510(k) – Device Modification

for the

I-Flow Variable Rate
Elastomeric Pump

Marketed by I-Flow Corporation

RECEIVED
2002 NOV 21 P 2:11
FDA/CDRH/ODE/PMO

FDA Original

SK 416
21

CDRH SUBMISSION COVER SHEET

Date of Submission: November 19, 2002

FDA Document Number:

Section A Type of Submission

PMA	PMA Supplement	PDP	510(k)	Meeting
<input type="checkbox"/> Original submission <input type="checkbox"/> Modular submission <input type="checkbox"/> Amendment <input type="checkbox"/> Report <input type="checkbox"/> Report Amendment	<input type="checkbox"/> Regular <input type="checkbox"/> Special <input type="checkbox"/> Panel Track <input type="checkbox"/> 30-day Supplement <input type="checkbox"/> 30-day Notice <input type="checkbox"/> 135-day Supplement <input type="checkbox"/> Real-time Review <input type="checkbox"/> Amendment to PMA Supplement	<input type="checkbox"/> Presubmission summary <input type="checkbox"/> Original PDP <input type="checkbox"/> Notice of intent to start clinical trials <input type="checkbox"/> Intention to submit Notice of Completion <input type="checkbox"/> Notice of Completion <input type="checkbox"/> Amendment to PDP <input type="checkbox"/> Report	<input checked="" type="checkbox"/> Original submission: <input type="checkbox"/> Traditional <input checked="" type="checkbox"/> Special <input type="checkbox"/> Abbreviated <input type="checkbox"/> Additional information: <input type="checkbox"/> Traditional <input type="checkbox"/> Special <input type="checkbox"/> Abbreviated	<input type="checkbox"/> Pre-IDE meeting <input type="checkbox"/> Pre-PMA meeting <input type="checkbox"/> Pre-PDP meeting <input type="checkbox"/> 180-day meeting <input type="checkbox"/> Other (specify):
IDE	Humanitarian Device Exemption	Class II Exemption	Evaluation of Automatic Class III Designation	Other Submission
<input type="checkbox"/> Original submission <input type="checkbox"/> Amendment <input type="checkbox"/> Supplement	<input type="checkbox"/> Original submission <input type="checkbox"/> Amendment <input type="checkbox"/> Supplement <input type="checkbox"/> Report	<input type="checkbox"/> Original submission <input type="checkbox"/> Additional information	<input type="checkbox"/> Original submission <input type="checkbox"/> Additional information	Describe submission:

Section B Applicant or Sponsor

Company / Institution name: I-Flow Corporation	Establishment registration number: 2026095	
Division name (if applicable):	Phone number (include area code): <input type="text"/>	
Street address: 20202 Windrow Drive	FAX number (include area code): <input type="text"/>	
City: Lake Forest	State / Province CA	Country: U.S.A.
Contact name: <input type="text"/>		
Contact title: Executive Vice President and COO	Contact e-mail address: <input type="text"/>	

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: Director, Regulatory Affairs	Contact e-mail address: shane.noehre@i-flowcorp.com	

SK 46 22

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

- | | | |
|---|---|---|
| <input type="checkbox"/> New device
<input type="checkbox"/> Withdrawal
<input type="checkbox"/> Additional or expanded indications
<input type="checkbox"/> Licensing agreement

<input type="checkbox"/> Process change
<input type="checkbox"/> Manufacturing
<input type="checkbox"/> Sterilization
<input type="checkbox"/> Packaging
<input type="checkbox"/> Other (specify below)

<input type="checkbox"/> Response to FDA correspondence:
<input type="checkbox"/> Request for applicant hold
<input type="checkbox"/> Request for removal of applicant hold
<input type="checkbox"/> Request for extension
<input type="checkbox"/> Request to remove or add manufacturing site

<input type="checkbox"/> Other reason (specify): | <input type="checkbox"/> Change in design, component, or specification:
<input type="checkbox"/> Software
<input type="checkbox"/> Color Additive
<input type="checkbox"/> Material
<input type="checkbox"/> Specifications
<input type="checkbox"/> Other (specify below)

<input type="checkbox"/> Labeling change:
<input type="checkbox"/> Indications
<input type="checkbox"/> Instructions
<input type="checkbox"/> Performance Characteristics

<input type="checkbox"/> Shelf life
<input type="checkbox"/> Trade name
<input type="checkbox"/> Other (specify below) | <input type="checkbox"/> Location change:
<input type="checkbox"/> Manufacturer
<input type="checkbox"/> Sterilizer
<input type="checkbox"/> Packager
<input type="checkbox"/> Distributor

<input type="checkbox"/> Report submission:
<input type="checkbox"/> Annual or periodic
<input type="checkbox"/> Post-approval study
<input type="checkbox"/> Adverse reaction
<input type="checkbox"/> Device defect
<input type="checkbox"/> Amendment

<input type="checkbox"/> Change in ownership
<input type="checkbox"/> Change in correspondent |
|---|---|---|

Section D2**Reason for Submission — IDE**

- | | | |
|--|--|--|
| <input type="checkbox"/> New device
<input type="checkbox"/> Addition of institution
<input type="checkbox"/> Expansion / extension of study
<input type="checkbox"/> IRB certification
<input type="checkbox"/> Request hearing
<input type="checkbox"/> Request waiver
<input type="checkbox"/> Termination of study
<input checked="" type="checkbox"/> Withdrawal of application
<input type="checkbox"/> Unanticipated adverse effect
<input type="checkbox"/> Notification of emergency use
<input type="checkbox"/> Compassionate use request
<input type="checkbox"/> Treatment IDE
<input type="checkbox"/> Continuing availability request

<input type="checkbox"/> Other reason (specify): | <input type="checkbox"/> Change in:
<input type="checkbox"/> Correspondent
<input type="checkbox"/> Design
<input type="checkbox"/> Informed consent
<input type="checkbox"/> Manufacturer
<input type="checkbox"/> Manufacturing process
<input type="checkbox"/> Protocol - feasibility
<input type="checkbox"/> Protocol - other
<input type="checkbox"/> Sponsor

<input type="checkbox"/> Report submission:
<input type="checkbox"/> Current investigator
<input type="checkbox"/> Annual progress
<input type="checkbox"/> Site waiver limit reached
<input type="checkbox"/> Final | <input type="checkbox"/> Response to FDA letter concerning:
<input type="checkbox"/> Conditional approval
<input type="checkbox"/> Deemed approved
<input type="checkbox"/> Deficient final report
<input type="checkbox"/> Deficient progress report
<input type="checkbox"/> Deficient investigator report
<input checked="" type="checkbox"/> Disapproval
<input type="checkbox"/> Request extension of time to respond to FDA
<input type="checkbox"/> Request meeting |
|--|--|--|

Section D3**Reason for Submission — 510(k)**

- | | | |
|--|---|--|
| <input type="checkbox"/> New device
<input type="checkbox"/> Additional or expanded indications
<input type="checkbox"/> Other reason (specify): | <input type="checkbox"/> Change in technology
<input checked="" type="checkbox"/> Change in design | <input type="checkbox"/> Change in materials
<input type="checkbox"/> 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 K020660	1 Elastomeric Infusion Pump	1 I-Flow Corporation
2	2	2
3	3	3
4	4	4
5	5	5
6	6	6

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, KVO	1 various
2	2
3	3
4	4
5	5

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

1 K020660	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	Device class: <input type="checkbox"/> Class I <input checked="" type="checkbox"/> Class II <input type="checkbox"/> Class III <input type="checkbox"/> Unclassified
Classification panel: General Hospital		

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

24

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

<input checked="" type="checkbox"/> Original <input type="checkbox"/> Add <input type="checkbox"/> Delete	FDA establishment registration number: 2026095	<input checked="" type="checkbox"/> Manufacturer <input type="checkbox"/> Contract manufacturer	<input type="checkbox"/> Contract sterilizer <input type="checkbox"/> 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: Director, Regulatory Affairs		Contact e-mail address: shane.noehre@i-flowcorp.com	
<input type="checkbox"/> Original <input type="checkbox"/> Add <input type="checkbox"/> Delete	FDA establishment registration number:	<input type="checkbox"/> Manufacturer <input type="checkbox"/> Contract manufacturer	<input type="checkbox"/> Contract sterilizer <input type="checkbox"/> 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:	
<input type="checkbox"/> Original <input type="checkbox"/> Add <input type="checkbox"/> Delete	FDA establishment registration number:	<input type="checkbox"/> Manufacturer <input type="checkbox"/> Contract manufacturer	<input type="checkbox"/> Contract sterilizer <input type="checkbox"/> 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:	



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

November 19, 2002

Via Federal Express

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

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 2002 NOV 21 P 2:11
 FDA/CDRH/ODE/PMO

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.

The I-Flow Variable Rate Elastomeric Pump was cleared earlier this year on March 20, 2002 under K020660. This notification is being submitted to propose a labeling modification due to a design change. Please note that the I-Flow Variable Rate Elastomeric Pump has not been introduced into interstate commerce for commercial distribution.

No changes will be made to the indications for use, sterilization, fundamental scientific technology or packaging.

This premarket notification will repeat the Variable Flow Rate information from the previous submission (K020660) for ease of review. The following changes/additions have been included:

1. Risk Assessment Addendum
2. Directions for Use
3. Flow rate specification change of

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

Shane Noehre
 Director of Regulatory Affairs

Sincerely,

Shane Noehre, RAC
 Director, 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

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- Appendix B – Example Homepump Drawing**
- Appendix C – Example Homepump Labeling**
 - *Changed Directions for Use*
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- Appendix E – Summary of Safety and Effectiveness**

**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.



Name	Title
<u>I-Flow Corporation</u>	<u>11/19/02</u>
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: 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.
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(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.

Chief Operating Officer
I-Flow Corporation

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: at 95% confidence interval.
2. Leak Testing: no leaks
3. Residual Volume: ml depending on model
4. Bond Strength: >
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
2. Risk Benefit Assessment: Addendum to

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 labeling modification to our own legally marketed device. The change affects the variable flow rate component cleared under K020660 for the Homepump.
- 1.1.2 The labeling modification is due to a design change. It appears that the variable flow rate component when attached to the Homepump device will not be able to meet the accuracy as stated in K020660. I-Flow ~~proposes to change the labeling for the accuracy specification to [] at 95% confidence interval instead of [] at 95% confidence interval.~~
- 1.1.3 Please note that the Variable Rate Homepump has not been introduced into interstate commerce for commercial distribution.
- 1.1.4 No changes will be made to the indications for use, sterilization, fundamental scientific technology, packaging or pump.
- 1.1.5 Common Name: Infusion Pump
- 1.1.6 Classification Name: Pump, Infusion
- 1.1.7 Product Code: MEB
- 1.1.8 Device Classification: Class II, 880.5725
- 1.1.9 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 50 to 500 ml.
- 2.2.2 The [] function as the fluid reservoir and the pressure source.
- 2.2.3 The pressure that pumps the fluid comes [] which are forced to [] filled.
- 2.2.4 The incorporation of [] produces the desired flow rate. The administration line may incorporate any of the following optional components:

2.2.4.1 [redacted]

2.2.5 The Variable Flow Component:

2.2.5.1 This component [redacted] which can [redacted] from a dial. The dial is labeled with each flow rate and a [redacted] As a flow rate [redacted] 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 [redacted] As the dial is turned, [redacted] which varies the flow rate. For example, [redacted] As the dial is moved from one labeled flow rate to the next the following occurs:

Dial Position	Net Flow Rate (ml/hr)
[redacted]	[redacted]

Thus the [redacted] off. [redacted] and the remaining two tubings remain pinched off which [redacted] When dialed to [redacted] ml/hr tubing is pinched off and the [redacted] which results in [redacted] When [redacted] [redacted] tubings are opened and the [redacted] which results in a total of [redacted] 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 K020660.

2.3.2 Each administration line consists [redacted]
[redacted]

2.3.3 The [redacted]
When the pump is filled and pressurized, the flow rates are approximated by [redacted]

[redacted]

2.3.4 Where Q is the flow rate, ρ is the pressure drop [redacted] D is the inside diameter [redacted] μ is the dynamic viscosity of the fluid and L is the length [redacted]. 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 [redacted] 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: combination [redacted]

3.1.1.1 [redacted]

3.1.2 Model 2: combination of 1.0, 2.0 and 4.0 ml/hr flow control tubing yields:

3.1.2.1 [redacted]

3.1.3 Model 3: combination [redacted]

3.1.3.1 [redacted]

4.0 COMPONENTS AND MATERIALS

Note: [redacted] 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:

Residual Volume: [redacted] depending on model

Operating Temperature: [redacted] for Variable Flow Rate set

Test Solution: [redacted]

Operating Pressure: approximately 10 psi pressure source

Accuracy: [redacted] at 95% confidence interval

5.2 **Power Requirements:** The Homepump is a mechanical device that utilizes the strain energy of the [redacted] which are forced to expand when the [redacted]. No [redacted] 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

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 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.
- 8.3 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.
- 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 labeling will be to the accuracy of the variable flow rate component when attached to the Homepump. The accuracy specification will be changed from at 95% confidence interval to at 95% confidence interval.
- 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 [redacted]
- 11.4 [redacted] on the Tyvek pouch. The results of [redacted] 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 [redacted]
- 12.3 Sterilization validation methodology is [redacted]
[redacted]
 - 12.3.1 [redacted]
- 12.4 Sterilization validation methodology is [redacted]
[redacted]
 - 12.4.1 [redacted]
 - 12.4.2 [redacted]

12.5 The sterile product under review here will have a sterilization assurance level (SAL) of 10^{-6} . [redacted] Under [redacted]
[redacted]

12.6 The Homepump is labeled pyrogen free and is [redacted]
[redacted]

12.6.1 I-Flow products have been validated for [redacted]

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 K020660.

*new component
??*

13.3 Operational Specifications

13.3.1 The operational specifications for the variable flow rate sets are the same as the existing (unmodified) Homepump except for the
[redacted]

13.3.2 The variable flow rate sets are [redacted] and the existing (unmodified) low flow rate Homepump are [redacted] temperature as the [redacted]

13.3.3 It appears that the variable flow rate component when attached to the unmodified Homepump device [redacted] stated in K020660. The accuracy specification for the variable flow rate device will be changed to [redacted] at 95% confidence interval and the existing (unmodified) Homepump has a [redacted] at 95% confidence interval specification.

13.3.4 No change in sterilization or packaging.

Appendix A
Risk Assessment







✓

✓

✓



•
•
•

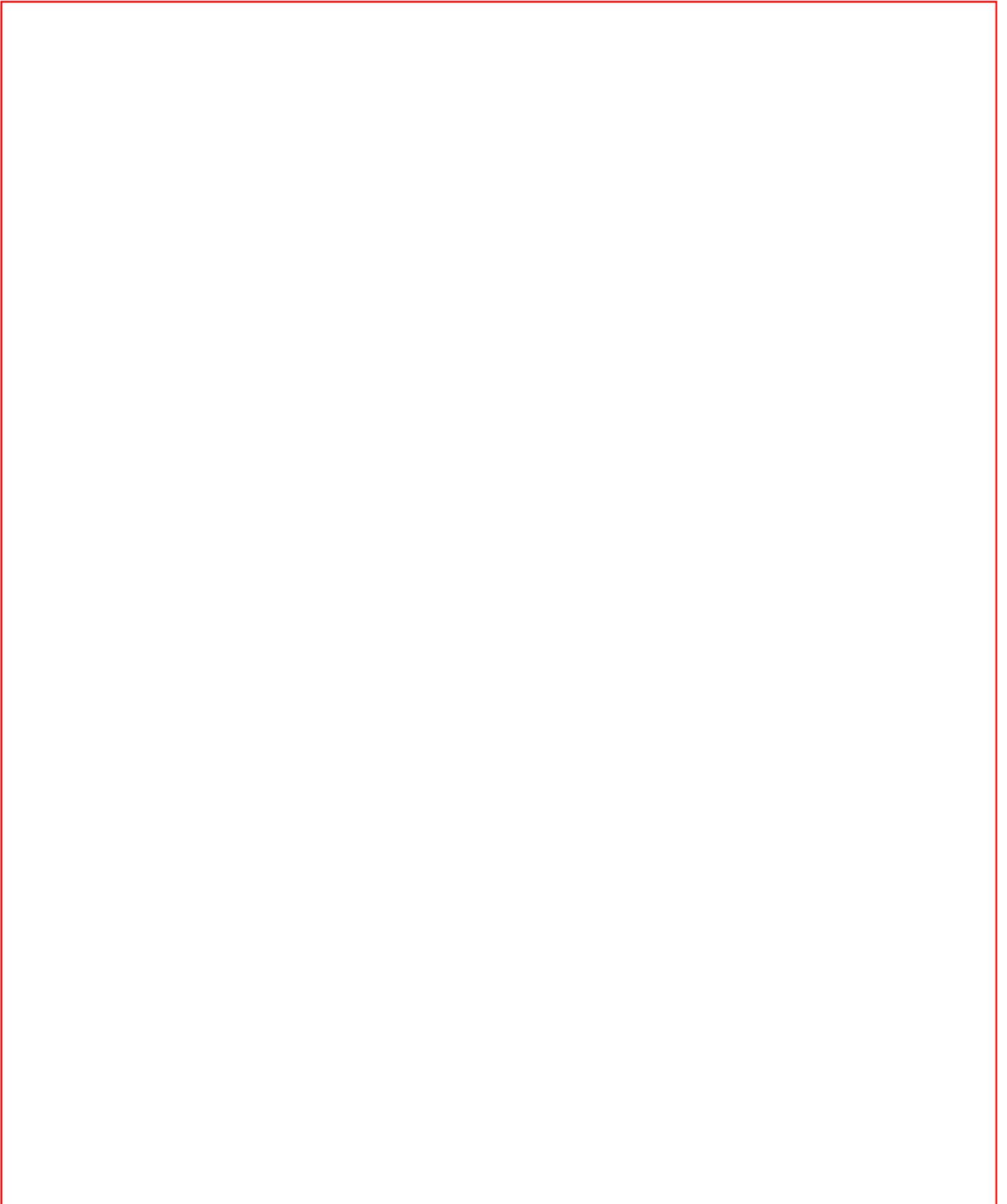


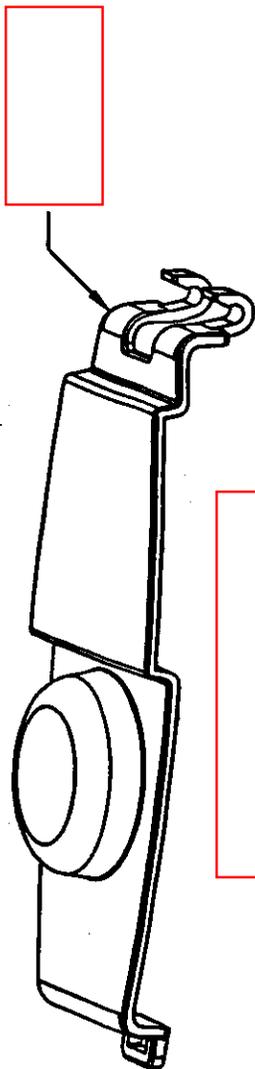


45

Appendix B
Drawings







Appendix C
Example Labeling

Models: CV100035, CV270070, CV500140

Homepump® Eclipse C-Series

Elastomeric Infusion System

with

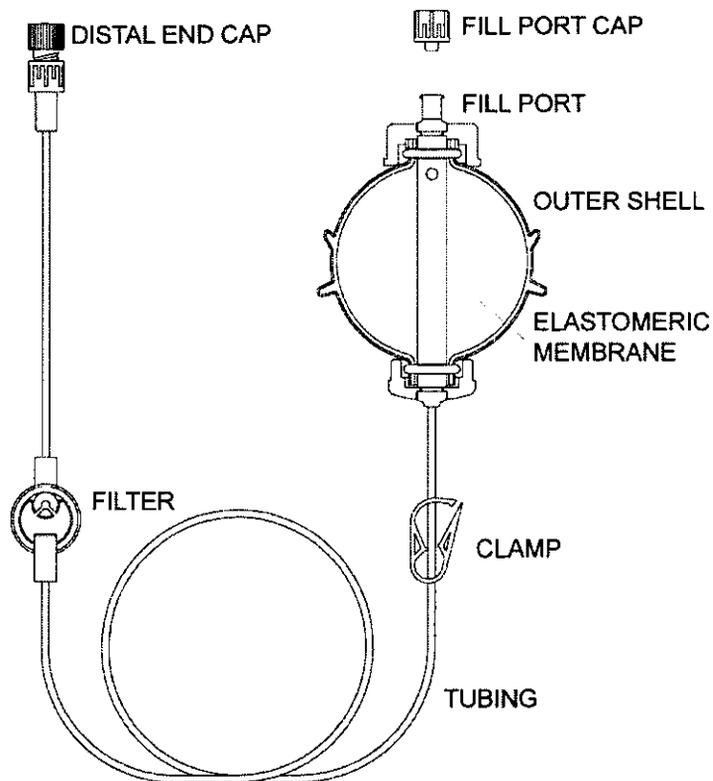
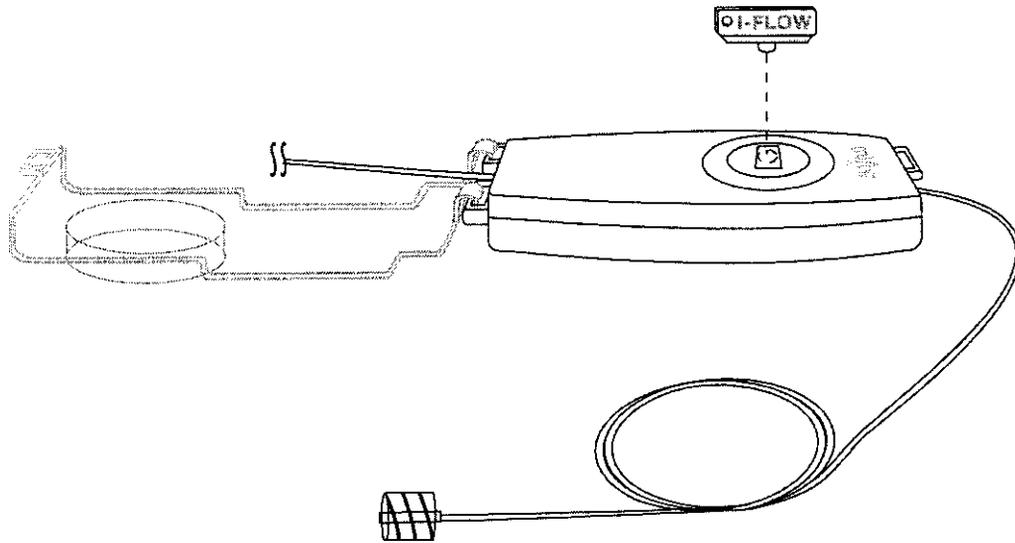
Select-A-Flow™
Variable Rate Controller

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

NOTE: The Select-A-Flow controller is an integrated part of the pump. At this time, we don't have a picture with the controller as part of the Homepump tubing. This picture will of course be completed prior to market distribution.



Homepump Eclipse C-Series Disposable Elastomeric Infusion System®
with *Select-A-Flow™* Variable Rate Controller

DIRECTIONS FOR USE

NOMENCLATURE

- ① *Homepump Elastomeric* Infusion Pump
- ② *Select-A-Flow* Variable Rate Controller
- ③ Pinch Clamp
- ④ Filter 1.2 micron, air-eliminating
- ⑤ Flow Rate Dial
- ⑥ Rate-Changing Key
- ⑦ Lockable Cover
- ⑧ Fill Port

INDICATIONS FOR USE

The *Select-A-Flow* models incorporate 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 Homepump is a disposable elastomeric infusion pump that is intended for delivery of medications for general infusion use, including chemotherapy and pain management. Routes of administration include intravenous, intra-arterial, subcutaneous, intramuscular, epidural, intraoperative, perineural, and percutaneous.

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 Homepump is to be used for epidural drug administration, it should be labeled to differentiate from other routes of administration. Do not use a Y-adaptor for epidural delivery. When using the Homepump for epidural drug delivery, make certain only drugs recommended for this route of administration are used.
4. Do not resterilize the Homepump. The pumps are intended for single use only. The fluid pathway is sterile and nonpyrogenic. It is recommended that the pump 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 *HOME PUMP*

CAUTION: Use Aseptic Technique

1. Remove the Homepump with the attached *Select-A-Flow* from its package.
2. Remove the cap from the fill 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 Table 1).
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.

CAUTION: The nominal infusion volume for each Homepump is labeled on the fill port.

PRIMING THE VARIABLE RATE ADMINISTRATION SET Use Aseptic Technique

1. Allow Homepump to warm to room temperature before using.
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.
4. Open the clamp and remove the cap from the luer lock at the end of the set.
5. Medication will flow toward the end of the set.
6. 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, \emptyset , off position and replace the cap on the end of the *Select-A-Flow* Administration Set.

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

STARTING THE INFUSION

1. Connect the Homepump tubing to the patient's access site. 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: Insure 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.

Delivery Time Information for the Homepump Infusion System with *Select-A-Flow*
Table 1

Product Information			
Homepump Models	CV100035	CV270070	CV500140
Nominal Fill Volume	100 ml	270 ml	500 ml
Maximum Fill Volume	125 ml	335 ml	550 ml
Flow Rate Range (ml/hr)	0.5 to 3.5	1 to 7	2 to 14
Retained Volume	≤ 6	≤ 9	≤ 15
Time to Reach Room Temperature			
Hours from refrigerator	12	12	18

When filled to nominal volume, delivery accuracy is ± 20% (at a 95% confidence interval) of the labeled infusion rate when delivering normal saline at 72° F (21°C) against a back pressure of 40 cm of water.

CAUTIONS

- Actual infusion times may vary due to the following:
 - Filling the Homepump less than nominal results in faster flow rate.
 - Filling the Homepump more than nominal results in slower flow rate.
 - Positioning the Homepump above (flow rate increases) or below (flow rate decreases) the catheter site.
 - Temperature will affect solution viscosity, resulting in shorter or longer delivery time. The Homepump with *Select-A-Flow* 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 Homepump delivery should be started within 8 hours of filling. Storage of a filled Homepump unit for more than 8 hours prior to starting infusion may result in a 10%

longer delivery time.

- If the Homepump unit needs to be stored in the refrigerator for any reason, allow the unit to warm to room temperature before using. Refer to Table 1: Delivery Time Information, for the required information to meet room temperature.
Note: Delivery time can increase significantly as a result of extended storage time.
- The Homepump nominal flow rates are based on the use of normal saline as the diluent. Addition of any drug or use of another diluent may change viscosity and result in increased or decreased flow rate. Use of 5% dextrose will result in 10% longer delivery time.
- When administering through a central or peripheral catheter, follow instructions provided by the catheter manufacturer. Peripherally inserted central catheter (PICC) lines smaller than 20 gauge x 56 mm (or other restrictive devices) will decrease flow rate.
- Avoid getting detergents (like soap) on the filter, which may cause leakage from the air-eliminating vent.
- Roll tubing between fingers to promote flow if clamped for extended time.
- Do not freeze the Homepump with *Select-A-Flow*. Testing under these temperature conditions has not been conducted.
- 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 thorough understanding of possible incompatibility problems.

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: $\pm 20\%$ at a 95% confidence interval.

Residual Volume: 6 – 15 ml depending on model.



Outside the USA or for I-Flow Corporation:

949.206.2700

or:

www.i-flowcorp.com

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

TM Select-A-Flow is a trademark of I-Flow Corporation registered with the U.S. Patent and Trademark Office. U.S. and Foreign Patents pending.



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



0123

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

U.S. and Foreign Patents Pending.



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.



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

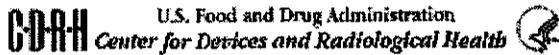


0123

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

U.S. and Foreign Patents Pending.

Appendix D
Homepump Regulatory Documentation



Prototype - for testing only

[510 \(k\)](#) | [Registration](#) | [Listing](#) | [Adverse Events](#) | [PMA](#) | [Classification](#) | [CLIA](#)
[CFR Title 21](#) | [Advisory Committees](#) | [Assembler](#) | [NHRIC](#) | [Guidance](#) | [Standards](#)

[New Search](#)

[Back To Search Results](#)

Product Classification Database

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
- ENTECLA, INC.
- INTERTEK TESTING SERVICES
- N.V. KEMA
- TUV AMERICA, INC.
- TUV RHEINLAND OF NORTH AMERICA, INC.
- UNDERWRITERS LABORATORIES, INC.

Database Updated 11/5/2002



Prototype - for testing only

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[CFR Title 21](#) | [Advisory Committees](#) | [Assembler](#) | [NHRIC](#) | [Guidance](#) | [Standards](#)

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510(k) Premarket Notification Database

Device Classification Name	PUMP, INFUSION, ELASTOMERIC
Regulation Number	880.5725
510(k) Number	K020660
Device Name	HOME PUMP, ECLIPSE, C-SERIES, PAINBUSTER, C-BLOC,
Applicant	I-FLOW CORP. 20202 WINDROW DR. LAKE FOREST, CA 92630
Contact	SHANE NOEHRE
Product Code	MEB
Date Received	03/01/2002
Decision Date	03/20/2002
Decision	SUBSTANTIALLY EQUIVALENT (SE)
Classification Advisory Committee	General Hospital
Review Advisory Committee	General Hospital
Statement/Summary/Purged Status	Summary only
SUMMARY/Approval Letter Type	<u>SUMMARY</u> Special
Reviewed by Third Party	No
Expedited Review	No

Database Updated 11/5/2002



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 20 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,



Timothy A. Ulatowski

Director

Division of Dental, Infection Control
and General Hospital Devices

Office of Device Evaluation

Center for Devices and
Radiological Health

Enclosure



I-Flow Corporation

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Lake Forest, CA 92630
Tel: 800.448.3569 or 949.206.2700
Fax: 949.206.2600
www.i-flowcorp.com

K020660

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)

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

Appendix E
Summary of Safety and Effectiveness

SPECIAL 510(K) - SUMMARY OF SAFETY AND EFFECTIVENESS

December 18, 2002

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

Contact: Shane Noehre
Director, 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 (K020660)

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 labeling change to the existing device submitted under K020660 for the variable flow rate component.

Technology Comparison: The Variable Flow Rate Component is identical in design to the one recently cleared under K020660.

Conclusion: The I-Flow Variable Rate Elastomeric Pump was cleared under K020660 on March 20, 2002. It was found to be substantially equivalent to the existing I-Flow Elastomeric Pump and the variable flow rate component cleared under K020251.

Memorandum

From: Reviewer(s) - Name(s) Howe Zamora

Subject: 510(k) Number 15023883

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)

Animal Tissue Source 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 day

Predicate Product Code with class:

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

II MED 886.5725

Review: Patricia Piccinini 11/20/02
(Branch Chief) (Branch Code) (Date)

Final Review: [Signature] 12/20/02
(Division Director) (Date)

SPECIAL 510(k): Device Modification
ODE Review Memorandum (Decision Making Document is Attached)

To: THE FILE

RE: DOCUMENT NUMBER K 023883

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 a device modification of a variable flow rate component. This modification requires a
to plus/minus
4. **Comparison Information** (similarities and differences) to applicant's legally marketed predicate device including, labeling, intended use, physical characteristics, and **the modified set is calibrated at**
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.

Louis Samura

(Reviewer's Signature)

12/19/02
(Date)

Comments

revised:3/27/98

Memo to the record

Subject: I-Flow Variable Rate Elastomeric Pump (K023883) by I-Flow Corporation

[Redacted]

- We called Mr. Shane Noehre and Requested to add a caution from K023098.
- The company sent a reply by FAX as attachment 1.

[Redacted]

- We called him again to modify the proposed caution and the company agreed with it as attachment 2. We also clarified the trade name.
- The summary of safety and effectiveness has been changed.

[Redacted]

12/19/02

Attachment 1



I-FLOW CORPORATION

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

The documents accompanying this facsimile transmission contains information which may be legally privileged and confidential. The information is intended only for the use of the recipient named below. If you have received this facsimile in error, please immediately notify us by telephone to arrange for return of the original documents to us. Any disclosure, copying, distribution or taking of any action in reliance on the contents of this faxed information is strictly prohibited.

Fax

To: **From:** Shane Noehre

Company: FDA **Pages:** 2

Fax: **Date:** 12/17/2002

Phone: **CC:**

Subject: K023883

- Urgent For Review Please Comment Please Reply Please Recycle

• Comments:

Please see attached letter.

Shane Noehre
Director, Regulatory Affairs
I-Flow Corporation
Tel: (949) 206-2653, Fax: (949) 206-2600
E-mail: shane.noehre@i-flowcorp.com



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

Re: K023883

Dear [redacted]

This letter is in regards to our phone conversation on December 17, 2002. As requested, below is the proposed caution statement for K023883 and the reason for changing the accuracy of K023883.

[FDA proposed statement]

CAUTION: Please be aware that the actual flow rate at which the medication is delivered and total amount of medication the patient receives [redacted] depending on reservoir size and chosen flow rate. Please take this variance of medication delivery into consideration in determining both the flow rate and duration of delivery of medication in order to reduce the probability of an adverse event.

[I-Flow proposed statement]

CAUTION: The selected flow rate [redacted] Please take this variance into consideration when determining medication delivery to reduce potential adverse events.

We tried to make the statement concise yet carry your original intent. We reduced prepositional phrases whenever possible. We eliminated redundant and/or synonymous words/phrases. For example, "Please be aware" is synonymous with [CAUTION]. Also we simplified the confusing verbiage on medication delivery as any healthcare professional using an infusion pump understands that pump volume and flow rate dictate the delivery time as this is fundamental to their practice of medicine. I was confused by reading the first statement and truly believe the second statement is easy to read, meaningful and true to the original intent.

K023883 was submitted to change the [redacted] We originally believed in the design and development process that that we could achieve $\pm 15\%$ accuracy; however, it now looks like it will more closely be [redacted] Thus, I-Flow submitted a second 510(k) to state the new accuracy specification. If we can achieve the [redacted] specification at a future date, then I-Flow will revert to the original 510(k) (K020660) for market clearance.

Please let me know if you have any questions.

Sincerely,

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

attachment 2



20202 Windrow Drive
Lake Forest, CA 92630
Phone (949) 206-2700
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Fax (949) 206-2600

I-FLOW CORPORATION

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Fax

To:	Mr. Harry Sauberman	From:	Shane Noehre
Company:	FDA	Pages:	3
Fax:	301.480.3002	Date:	12/18/2002
Phone:	301.443.8879	CC:	
Subject:	K023883		

Urgent For Review Please Comment Please Reply Please Recycle

● **Comments:**

Please see attached letter.

Shane Noehre
Director, Regulatory Affairs
I-Flow Corporation
Tel: (949) 206-2653, Fax: (949) 206-2600
E-mail: shane.noehre@i-flowcorp.com



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

Re: K023883

Dear Mr. Sauberman:

This letter is in regards to our phone conversation on December 18, 2002. As requested, below is the caution statement for K023883 that will added to our labeling and that we agreed to implement.

CAUTION: The amount of medication over the therapeutic period and delivery time can vary by as much as 20% due to the flow rate variation. Please take this variance into consideration when determining medication delivery to reduce potential adverse effects.

Also, the name of the device is "I-Flow Variable Rate Elastomeric Pump". I've enclosed a new Summary of Safety and Effectiveness page to correct the name on the header.

Sincerely,

A handwritten signature in cursive script that reads "Shane Noehre".

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

SPECIAL 510(K) - SUMMARY OF SAFETY AND EFFECTIVENESS

December 18, 2002

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

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

Trade Name: I-Flow Variable Rate Elastomeric Pump

Common Name: Infusion Pump and Administration Set

Classification Name: Pump, Infusion

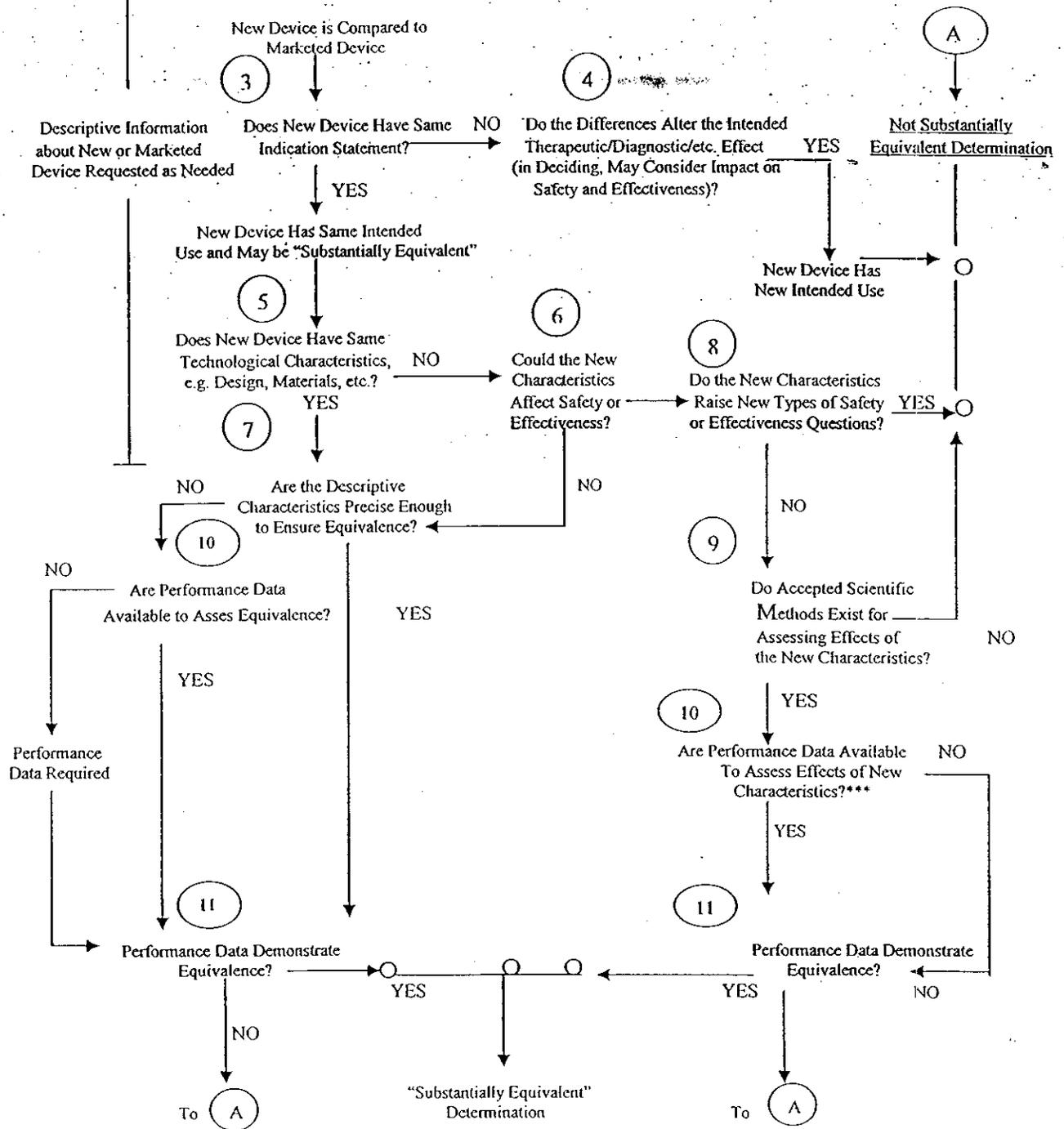
Existing Device: I-Flow Elastomeric Pump (K020660)

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 labeling change to the existing device submitted under K020660 for the variable flow rate component.

Technology Comparison: The Variable Flow Rate Component is identical in design to the one recently cleared under K020660.

Conclusion: The I-Flow Variable Rate Elastomeric Pump was cleared under K020660 on March 20, 2002. It was found to be substantially equivalent to the existing I-Flow Elastomeric Pump and the variable flow rate component cleared under K020251.

510(k) "SUBSTANTIAL EQUIVALENCE" DECISION-MAKING PROCESS



- ❖ 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.

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

510(k) Number: K023883

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 or Adequate	Missing or Inadequate
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.

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

	Present	Inadequate or Missing
Name and 510(k) number of the submitter'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 submitter's unmodified predicate device.	/	
Reviewer's confirmation that the modification has not altered the fundamental scientific technology of the submitter's predicate device.		
A Design Control Activities Summary that includes the following elements (a-c):		
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.	/	

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) boiler's 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 <u>not</u> 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 <u>and</u> 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.

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		
viii) Traditional Method or Non-Traditional Method		
c) Software Documentation:		

Items with checks in the "Present or Adequate" column do not require e additional information from the sponsor. Items with checks in the "Missing or Inadequate" column must be submitted before substantive review of the document.

Passed Screening Yes No
 Reviewer: Nora Zamora
 Concurrence by Review Branch: NOV 21

Date: _____

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>

REVISED:3/14/95

THE 510(K) DOCUMENTATION FORMS ARE AVAILABLE ON THE LAN UNDER 510(K) BOILERPLATES TITLED "DOCUMENTATION" AND MUST BE FILLED OUT WITH EVERY FINAL DECISION (SE, NSE, NOT A DEVICE, ETC.).

"SUBSTANTIAL EQUIVALENCE" (SE) DECISION MAKING DOCUMENTATION

K _____

Reviewer: _____

Division/Branch: _____

Device Name: _____

Product To Which Compared (510(K) Number If Known): _____

	YES	NO	
1. Is Product A Device	/		If NO = Stop
2. Is Device Subject To 510(k)?	/		If NO = Stop
3. Same Indication Statement?	/		If YES = Go To 5
4. Do Differences Alter The Effect Or Raise New Issues of Safety Or Effectiveness?			If YES = Stop NE
5. Same Technological Characteristics?	/		If YES = Go To 7
6. Could The New Characteristics Affect Safety Or Effectiveness?			If YES = Go To 8
7. Descriptive Characteristics Precise Enough?	/		If NO = Go To 10 If YES = Stop SE
8. New Types Of Safety Or Effectiveness Questions?			If YES = Stop NE
9. Accepted Scientific Methods Exist?			If NO = Stop NE
10. Performance Data Available?			If NO = Request Data
11. Data Demonstrate Equivalence?			Final Decision:

Note: In addition to completing the form on the LAN, "yes" responses to questions 4, 6, 8, and 11, and every "no" response requires an explanation.

1. Intended Use:
2. Device Description: Provide a statement of how the device is either similar to and/or different from other marketed devices, plus data (if necessary) to support the statement. Is the device life-supporting or life sustaining? Is the device implanted (short-term or long-term)? Does the device design use software? Is the device sterile? Is the device for single use? Is the device over-the-counter or prescription use? Does the device contain drug or biological product as a component? Is this device a kit? Provide a summary about the devices design, materials, physical properties and toxicology profile if important.

EXPLANATIONS TO "YES" AND "NO" ANSWERS TO QUESTIONS ON PAGE 1 AS NEEDED

1. Explain why not a device:
2. Explain why not subject to 510(k):
3. How does the new indication differ from the predicate device's indication:
4. Explain why there is or is not a new effect or safety or effectiveness issue:
5. Describe the new technological characteristics:
6. Explain how new characteristics could or could not affect safety or effectiveness:
7. Explain how descriptive characteristics are not precise enough:
8. Explain new types of safety or effectiveness questions raised or why the questions are not new:
9. Explain why existing scientific methods can not be used:
10. Explain what performance data is needed:
11. Explain how the performance data demonstrates that the device is or is not substantially equivalent:

ATTACH ADDITIONAL SUPPORTING INFORMATION

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 #191-2 and Federal Register 90N0332, September 10, 1991.		