USER: GRAY, ILKA K (ixg)

FOLDER: K023318 - 64 pages (FOI:08007474)

COMPANY: I-FLOW CORP. (IFLOW)

PRODUCT: PUMP, INFUSION, ELASTOMERIC (MEB)

SUMMARY: Product: I-FLOW ELASTOMERIC PUMP WITH BOLUS

DATE REQUESTED: Fri Nov 05 24:00:00 2010

DATE PRINTED: Tue Jan 04 07:25:23 2011

Note: Releasable Version

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SPECIAL 510(K) - SUMMARY OF SAFETY AND EFFECTIVENESS

October 3, 2002

OCT 1 8 2002

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

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

Trade Names: ON-Q, PainBuster, C-bloc, Eclipse, C-Series, Easypump, Homepump

Classification Name: Pump, Infusion, Elastomeric

Existing Device: I-Flow Elastomeric Pump (K020862)

Device Description: This special 510(k) proposes a new optional component for the I-Flow Elastomeric Pump that incorporates a bolus component. The bolus component offers the additional ability to deliver fixed bolus volumes of medication at fixed time intervals instead of just a continuous infusion rate.

Technology Comparison: The new Bolus Component utilizes the same technology for dispensing medication as the existing unmodified design.

Conclusion: The I-Flow Elastomeric Pump with Bolus is substantially equivalent to the existing I-Flow Elastomeric Pump.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 18 2002

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

Re: K023318
Trade/Device Name: I-Flow Elastomeric Pump with Bolus
Regulation Number: 21 CFR 880.5725
Regulation Name: Infusion Pump
Regulatory Class: II
Product Code: MEB
Dated: October 3, 2002
Received: October 4, 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 Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Ver/ 3 - 4/24/96

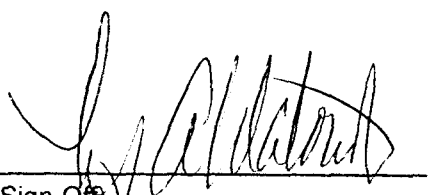
Applicant: I-Flow Corporation

510(k) Number (if known): K023318

Device Name: I-Flow Elastomeric Pump with Bolus

Indications For Use:

1. The I-Flow Elastomeric Pump with Bolus 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, subcutaneous, intramuscular and epidural.
2. The I-Flow Elastomeric Pump with Bolus is also intended for continuous and/or intermittent delivery of medication (such as local anesthetics or narcotics) to surgical wound sites and/o close proximity to nerves for preoperative, perioperative and postoperative regional anesthesia and pain management. Routes of administration may be intraoperative, perineural or percutaneous.



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

510(k) Number K023318

(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)

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 18 2002

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

Re: K023318
Trade/Device Name: I-Flow Elastomeric Pump with Bolus
Regulation Number: 21 CFR 880.5725
Regulation Name: Infusion Pump
Regulatory Class: II
Product Code: MEB
Dated: October 3, 2002
Received: October 4, 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.

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

Enclosure

Ver/ 3 - 4/24/96

Applicant: I-Flow Corporation

510(k) Number (if known): K023318

Device Name: I-Flow Elastomeric Pump with Bolus

Indications For Use:

1. The I-Flow Elastomeric Pump with Bolus 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, subcutaneous, intramuscular and epidural.
2. The I-Flow Elastomeric Pump with Bolus is also intended for continuous and/or intermittent delivery of medication (such as local anesthetics or narcotics) to surgical wound sites and/c close proximity to nerves for preoperative, perioperative and postoperative regional anesthesia and pain management. Routes of administration may be intraoperative, perineural or percutaneous.

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

510(k) Number: K023318

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Concurrence of CDRH, Office of Device Evaluation (ODE)

(Per 21 CFR 801.109)

(Optional Format 1-2-96)

3

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

October 04, 2002

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

510(k) Number: K023318
Received: 04-OCT-2002
Product: I-FLOW ELASTOMERIC PUMP WITH BOLUS

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
Center for Devices and Radiological Health

K 023318

Special 510(k) – Device Modification

for the

I-Flow Elastomeric Pump

Marketed by I-Flow Corporation

FDA Original

H 0 II

K#######

SM1

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CDRH Submission Cover Sheet

Date of Submission: October 3, 2002

FDA Document Number:

Section A Type of Submission

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

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

Section B Applicant or Sponsor

Company / Institution name: I-Flow Corporation

Establishment registration number: 2026095

Division name (if applicable):

Phone number (include area code): (b)(4) (b)(4)

Street address: 20202 Windrow Drive

FAX number (include area code): (b)(4) (b)(4)

City: Lake Forest State / Province CA Country: U.S.A.

Contact name: (b)(4) (b)(4)

Contact title: Executive Vice President and COO

Contact e-mail address (b)(4) (b)(4)

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): (b)(4) (b)(4)

Street address: 20202 Windrow Drive

FAX number (include area code): (b)(4) (b)(4)

City: Lake Forest State / Province: CA Country: U.S.A.

Contact name: Shane Noehre, RAC

Contact title: Director, Regulatory Affairs

Contact e-mail address: (b)(4) (b)(4)

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 MEA	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	K020862	I-Flow Elastomeric Pump	I-Flow Corporation
2	K992072	Bolus Accessory Set	I-Flow Corporation
3			
4			
5			
6			

Section F — Product Information — Applicable to All Applications

Common or usual name or classification name:
Pump, Infusion, Elastomeric

	Trade or proprietary or model name	Model number
1	I-Flow Elastomeric Pump with Bolus	various
2		
3		
4		
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

Device class:
- ☐ Class I
- ☑ Class II
- ☐ Class III
- ☐ Unclassified

Classification panel: General Hospital

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): (b)(4) (b)(4)	
Street address: 20202 Windrow Drive		FAX number (include area code): (b)(4) (b)(4)	
City: Lake Forest	State / Province: CA	Country: U.S.A.	
Contact name: Shane Noehre, RAC			
Contact title: Director, Regulatory Affairs		Contact e-mail address: (b)(4) (b)(4)	
☐ 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
USA

Tele: (800) 448-3569
(949) 206-2700
Fax: (949) 206-2600

Visit us on the web at:
www.I-FlowCorp.com
www.AskYourSurgeon.com

SPECIAL 510(k): Device Modification

October 3, 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

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 *I-Flow Elastomeric Pump* prior to the introduction into interstate commerce for commercial distribution.

I-Flow intends to market a new optional component for the I-Flow Elastomeric Pump. This new component is intended to allow bolus delivery and/or a basal flow rate.

This bolus component is similar to the one cleared under K992072. The new bolus component is more robust in design and easier for the healthcare provider or patient to use.

The existing (unmodified) *I-Flow Elastomeric Pump* has been cleared under K020862.

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 bolus component).

Another 510(k) will be submitted for I-Flow's Paragon Infusion System to incorporate the new Bolus Component option.

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

Shane Noehre
Director, Regulatory Affairs

Sincerely,

(b)(6)
(b)(6)

Shane Noehre, RAC
Director, Regulatory Affairs
I-Flow Corporation
20202 Windrow Dr
Lake Forest, CA 92630
Tel: (b)(4) (b)(4)
e-mail: (b)(4) (b)(4)

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3.0 Physical Specifications / Description of New Bolus Component ..... Page 7

4.0 Operational Specifications and Description ..... Page 8

5.0 Components and Materials ..... Page 9

6.0 Biocompatibility Specifications ..... Page 9

8.0 Indications for Use ..... Page 9

9.0 Labels and Labeling ..... Page 9

10.0 Packaging ..... Page 10

11.0 Sterilization ..... Page 10

12.0 Comparison to Existing (Unmodified) Device ..... Page 10

Appendix A – Risk Assessment for the Bolus Component (DCD1168A)

Appendix B – Bolus Component Drawings

Appendix C – Example Bolus Component Labeling

Appendix D – Predicate Regulatory Documentation: K020862 and K992072

Appendix E – Summary of Safety and Effectiveness

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

I certify that, in my capacity as the Executive Vice President and COO of I-Flow Corporation, I believe to the best of my knowledge, that all data and information submitted in the premarket notification for the I-Flow Elastomeric Pump with Bolus are truthful and accurate and that no material fact has been omitted.

(b)(6)
(b)(6)
(b)(6)
(b)(6)
Signature

(b)(4)
(b)(4)
Name

Executive Vice President and COO
Title

I-Flow Corporation
Company

14/3/02
Dated

Premarket Notification (510(k) Number)

Ver/ 3 - 4/24/96

Applicant: I-Flow Corporation

510(k) Number (if known): K023318

Device Name: I-Flow Elastomeric Pump with Bolus

Indications For Use:

1. The I-Flow Elastomeric Pump with Bolus 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, subcutaneous, intramuscular and epidural.
2. The I-Flow Elastomeric Pump with Bolus 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)

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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) (b)(6) 10/3/02

(b)(6) (b)(6) e Dated

(b)(6) (b)(6) 10/3/02

Signature Dated

(b)(4) (b)(4)

Executive Vice President and COO

I-Flow Corporation

(b)(4) (b)(4)

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. Average Basal Flow Rate Accuracy: (b)(4) (b)(4) confidence interval.
2. Average Bolus Volume Accuracy: (b)(4) (b)(4) confidence interval.
3. Average Refill Time Accuracy: (b)(4) (b)(4) confidence interval.
4. Leak Testing: no leaks when pressurized to (b)(4) (b)(4)
5. Residual Volume: (b)(4) (b)(4) depending on model volume.
6. Tubing Bond Strength: (b)(4) (b)(4)
7. Labeling: per section 8.0 of this submission.
8. Package Integrity: no changes to packaging.
9. Sterility: no changes to sterility.
10. Incoming Inspection: per the Risk Assessment.
11. In-process and Final Inspection: per the Risk Assessment.

Reference Documents

1. Risk Assessment for the Bolus Component (b)(4) (b)(4)

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1.0 GENERAL INFORMATION

1.1 Purpose of Submission

1.1.1 This submission is intended to notify the Federal Food and Drug Administration that I-Flow intends to make a device modification to our own legally marketed device. A new optional component for the I-Flow Elastomeric Pump will incorporate a bolus component.

1.1.2 The bolus component offers the additional ability to deliver fixed bolus volumes of medication at fixed time intervals instead of just a continuous infusion rate.

1.2 Statement of Equivalence

1.2.1 The existing (unmodified) I-Flow Elastomeric Pump has been cleared under K020862.

1.2.1.1 This new bolus component is similar to the one cleared under K992072. The new bolus component is more robust in design and easier for the healthcare provider or patient to use.

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

1.2.3 Common Name: Elastomeric Infusion Pump

1.2.4 Classification Name: Pump, Infusion, Elastomeric

1.2.5 Product Code: MEB

1.2.6 Device Classification: Class II, 880.5725

1.2.7 Medical Specialty: General Hospital

2.0 DESCRIPTION OF THE EXISTING (UNMODIFIED) DEVICE

2.1 The I-Flow Elastomeric Pump consists of an elastomeric pressure source with an integrated administration line. Fill volumes range from (b)(4) (b)(4) Flow rates range from (b)(4) (b)(4)

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

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.

2.4 The incorporation of (b)(4) (b)(4) with the elastomeric pressure source produces (b)(4) (b)(4) The administration line may incorporate any of the following optional components:

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

Note: All these features have been cleared under K020862.

2.5 The I-Flow Elastomeric Pump is suitable for use as an ambulatory device and is intended for use in hospitals, home environments or alternate care sites.

3.0 PHYSICAL SPECIFICATIONS/DESCRIPTION OF THE NEW BOLUS COMPONENT

3.1 Description

3.1.1 The Bolus Component controls the bolus and/or basal flow rate capability of the of the administration set that connects to the elastomeric pump.

3.1.2 The patient or healthcare provider simply presses a button to activate the bolus delivery. The refill time determines the amount of time the patient must wait prior to receiving another full bolus dose.

3.1.3 The Bolus Component (b)(4) (b)(4) It is ergonomically designed to easily grasp and curl the fingers around the device and activate the bolus button with a press from the thumb.

3.2 Models

The Bolus Components consists of various models that vary in bolus volume delivery, refill time between boluses and basal flow rate. (b)(4)

Bolus Vol (ml)	Refill Time (min)	Basal Flow Rate (ml/hr)
(b)(4)	(b)(4)	(b)(4)

3.3 The Bolus Chamber

3.3.1 The bolus chamber consists of a fixed maximum volume chamber.

3.4 Priming the Device

3.4.1 After the device has been primed, the bolus chamber immediately begins to fill with the refill time indicated by model.

3.5 Activating the Bolus

3.5.1 As the bolus button is pressed, (b)(4) (b)(4) (b)(4) (b)(4) button in a depressed position.

3.5.2 Simultaneously, a (b)(4) (b)(4) to allow the contents of the bolus chamber to be delivered to the patient.

3.5.3 The (b)(4) (b)(4) the bolus chamber until it reaches the bottom of the chamber upon which all medication has been delivered to the patient (about 20 seconds or less). When the bolus (b)(4) (b)(4) allow the bolus chamber to be refilled which begins immediately.

3.6 Bolus Refill Time

3.6.1 The bolus (b)(4) (b)(4) (b)(4) (b)(4) to the bolus chamber. This is same technology used

by the I-Flow Elastomeric Pump to deliver continuous medication to the patient.

3.6.2 For example, (b)(4) (b)(4) (b)(4) (b)(4)

3.7 Basal Flow Rate

3.7.1 Some models are equipped with a basal flow rate in addition to the bolus capability.

3.7.2 The basal flow rate is dictated by (b)(4) (b)(4) (b)(4) (b)(4) which leads directly to the patient.

3.8 **Flow Control**

3.8.1 The fundamental scientific technology for controlling the flow rate and refill time remains the same as the existing (unmodified) I-Flow Elastomeric Pump.

3.8.2 The flow restricting mechanism consists of a fixed diameter flow control glass orifice.

3.8.3 The flow control glass orifice is cut to a specific length L. When the pump is filled and pressurized, the flow rates are approximated (b)(4) (b)(4) (b)(4) (b)(4)

3.8.4 Where (b)(4) (b)(4) the pressure drop across (b)(4) (b)(4) is the inside diameter of the flow controlling (b)(4) (b)(4) dynamic viscosity of the fluid and (b)(4) (b)(4) The equation provides an approximation of the actual delivery time.

4.0 OPERATIONAL SPECIFICATIONS AND DESCRIPTONS

4.1 **Standard Operating Conditions:**

Priming/Residual Volume: (b)(4) (b)(4)
Operating Temperature:
Test Solution:
Operating Pressure:
Average Bolus Volume Accuracy: (b)(4) (b)(4)
Average Bolus Refill Time Accuracy:
Average Basal Flow Rate Accuracy:

4.2 **Power Requirements:** The I-Flow Elastomeric Pump with Bolus 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.

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4.3 **Safety/Alarm Functions**

4.3.1 The I-Flow Elastomeric Pump with Bolus provides fixed flow and as such is not subject to fluid runaway conditions similar to that of some electronic pumps.

4.3.2 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.

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

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

4.3.5 The device contains a mechanical indicator for the bolus chamber volume. After a bolus is given and during the bolus refill time, the indicator slowly moves from the empty position to the full position, indicating that the device can now deliver a full bolus when the button is pressed.

5.0 COMPONENTS AND MATERIALS

Note: No changes in materials will be made to the I-Flow Elastomeric Pump other than the Bolus Component. All the materials of the Bolus Component are of the same type used in other components of the I-Flow Elastomeric Pump and shall be in compliance with ISO (b)(4) (b)(4) prior to market distribution.

6.0 BIOCOMPATIBILITY SPECIFICATIONS

6.1 Biocompatibility testing is in conformance with ISO (b)(4) (b)(4) for all fluid path components based on intended application of the device prior to market distribution.

7.0 INDICATIONS FOR USE

7.1 There are no changes to the indications for use.

8.0 LABELS AND LABELING

8.1 The only change to the labeling will be for clarification on use of the Bolus Component.

8.2 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.

8.3 The I-Flow Elastomeric Pump with Bolus Directions for Use labeling:

8.3.1 Provides comprehensive directions for preparation and use for the I-Flow Elastomeric Pump with Bolus.

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

8.3.3 Contains warning information.

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

8.3.5 Includes the specifications of the I-Flow Elastomeric Pump with Bolus.

8.4 Identification labels and labeling

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8.4.1 There will be no change to the product identification labeling for the I-Flow Elastomeric Pump with Bolus other than new part numbers and cosmetic differences.

8.5 Packaging labels

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

9.0 PACKAGING

9.1 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).

10.0 STERILIZATION

10.1 There is no change in the sterilization methods.

11.0 COMPARISON TO THE EXISTING (UNMODIFIED) I-FLOW ELASTOMERIC PUMP

11.1 Indications for Use

11.1.1 No change in intended use.

11.2 Fundamental Scientific Technology

11.2.1 No change in technology.

11.2.2 The Bolus Component utilizes the same technology for dispensing medication as the existing unmodified design (i.e. precision glass orifice for basal (b)(4) (b)(4) chamber with button activation for bolus delivery). Reference K992072.

11.3 Operational Specifications

11.3.1 No change in specifications other than providing bolus capability.

11.4 No change in sterilization, packaging, or labeling (except for clarification).

11.5 Materials

11.5.1 The materials used in the I-Flow Elastomeric Pump with Bolus design are the same type as the predicate device covered in the previous premarket notifications.

11.6 **Conclusion:**

11.6.1 I-Flow Corporation believes that the new I-Flow Elastomeric Pump with Bolus design is substantially equivalent to the existing (unmodified) I-Flow Elastomeric Pump with bolus capability (Reference K992072).

Appendix A
Risk Assessment

Title: Risk Assessment for the Bolus Component

(b)(4)

(b)(4)

1.0 PURPOSE

(b)(4)

(b)(4)

2.0 SCOPE

(b)(4)

(b)(4)

3.0 REFERENCES

(b)(4)

(b)(4)

4.0 RISK ANALYSIS

(b)(4)

(b)(4)

(b)(4)

(b)(4)

5.0 RISK EVALUATION

(b)(4)

(b)(4)

(b)(4)

(b)(4)

6.0 RISK CONTROL

(b)(4)

(b)(4)

7.0 RISK MANAGEMENT REPORT

(b)(4)

(b)(4)

30

Table 1 - Failure Mode and Effect Analysis (FMEA)

Risk Assessment for Bolus Component

(b)(4)

Rev. A

(b)(4)

(b)(4)

(b)(4)

(b)(4)

31

Table Failure Mode and Effect Analysis (FMEA)

(b)(4)

(b)(4)

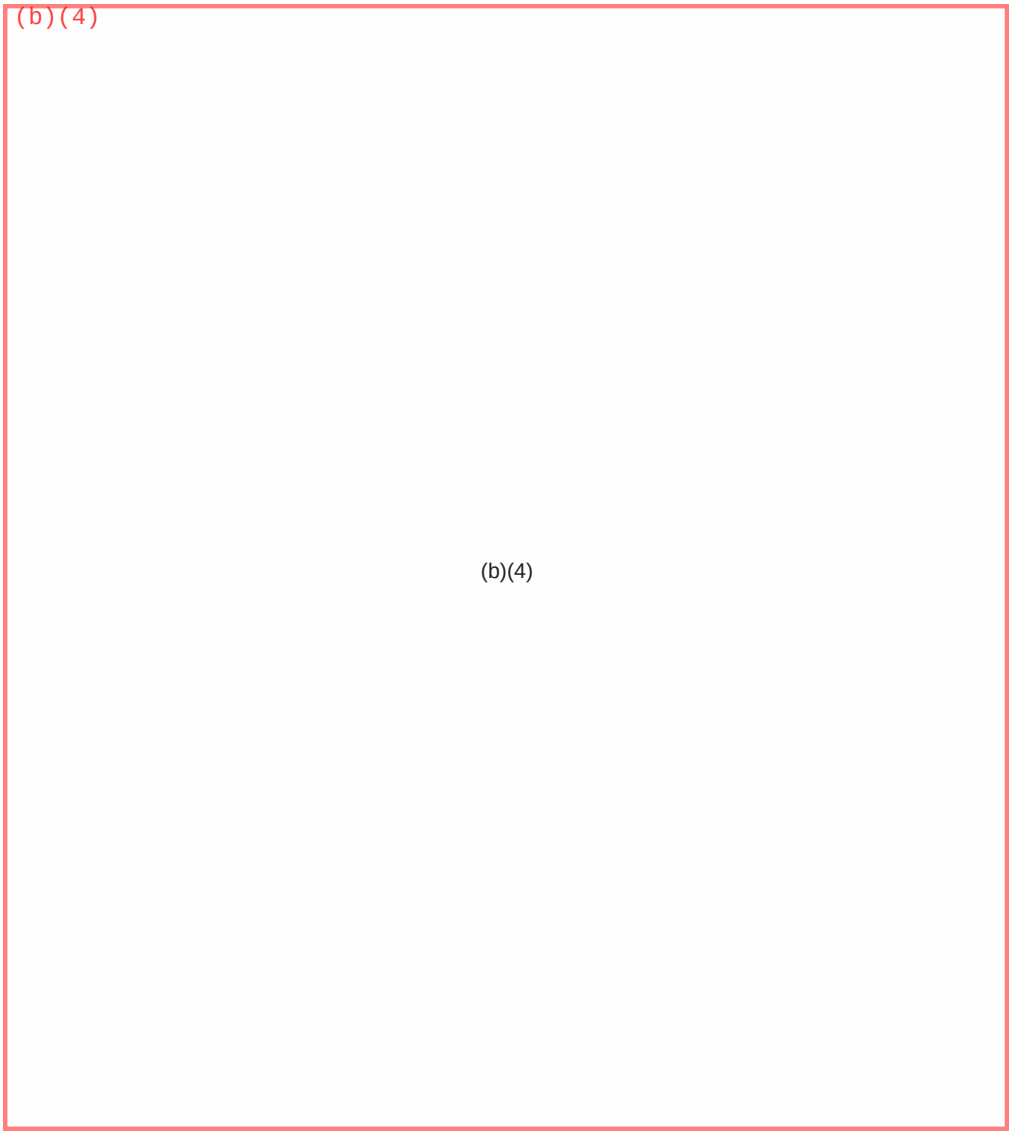
(b)(4)

(b)(4)

Appendix B
Drawings

Bolus Component

Cross Section Schematic



Appendix C
Example Labeling

MODELS

100-023002	100-053002	270-056005	270-053000
270-023002	270-053002	400-056005	400-106000

ON-Q® Post-Op Pain Relief

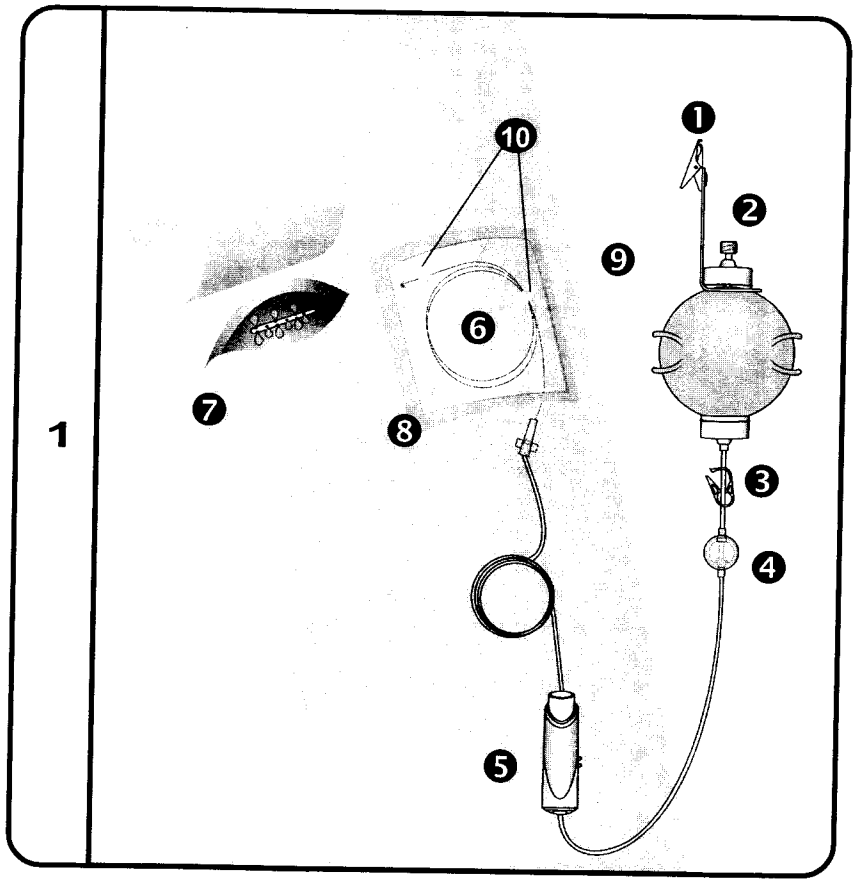
Soaker™

with Bolus

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



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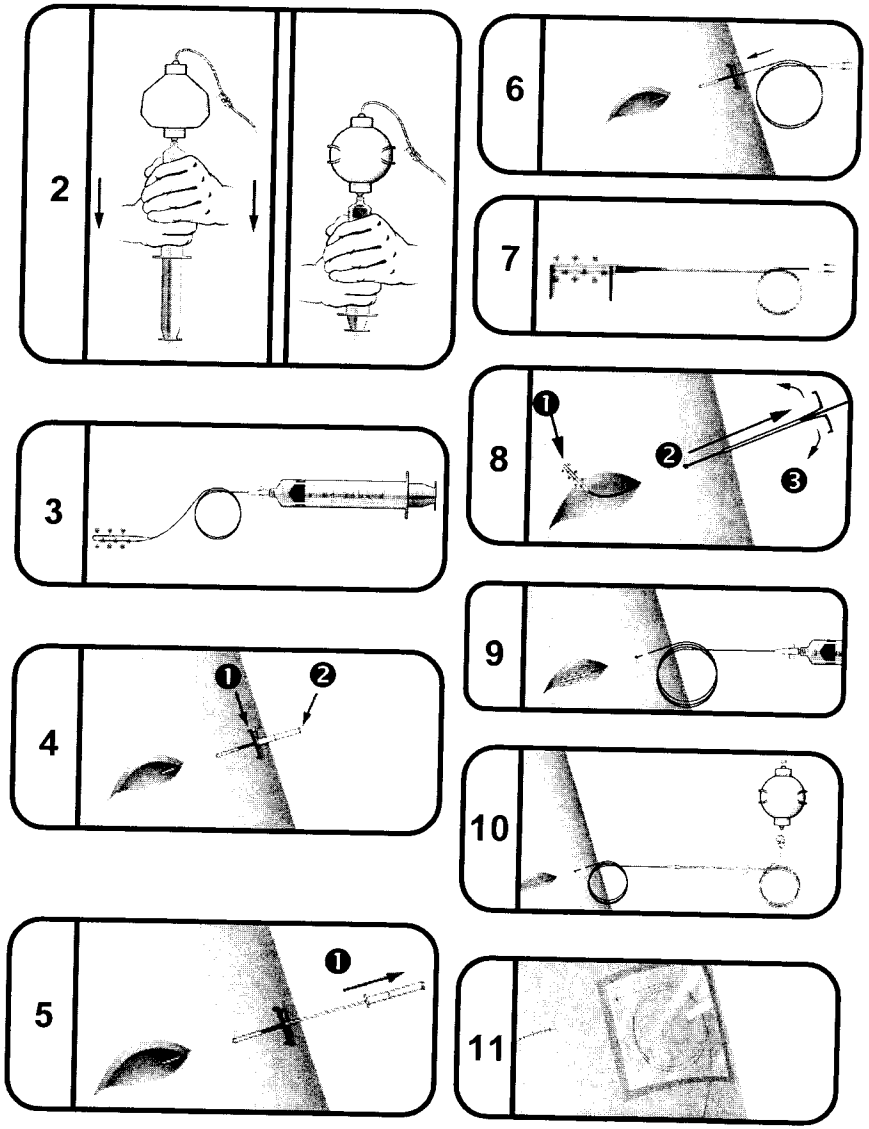

3

ILLUSTRATION AND NOMENCLATURE

Figure 1

❶ E-Clip
❷ Fill Port
❸ Clamp
❹ Filter
❺ Bolus Component
❻ Catheter
❼ Surgical Wound Site
❽ Dressing (not included)
❾ ON-Q Pump
❿ Adhesive Skin Closure Strip (not included)

INDICATIONS FOR USE

The ON-Q Soaker with Bolus Post-Op Pain Relief System is intended to provide continuous and/or intermittent infusion of a local anesthetic directly into an intraoperative site for postoperative pain relief. Infusions may also be administered percutaneously or perineurally.

The bolus component of the device allows fixed boluses to be delivered upon demand by the patient or healthcare provider. When the button is pressed, the labeled bolus is delivered in about 20 seconds or less and then the button returns to its original position at which time the bolus chamber begins to refill. During the refill time, the button may be pressed but only a partial bolus will be delivered.

DO NOT USE IF PACKAGE HAS BEEN OPENED, IS DAMAGED OR IF EITHER PROTECTOR CAP IS NOT IN PLACE. THE ON-Q SYSTEM IS STERILE AND NON-PYROGENIC. SINGLE USE ONLY. DO NOT RESTERILIZE.

CAUTIONS

- Do not exceed maximum fill volume of pump.
- Use of vasoconstrictors such as Epinephrine or adrenaline is not necessary and may not be recommended for continuous infusions.
- Medications used with this system should be administered in accordance with instructions provided by the drug manufacturer.
- Do not withdraw catheter through needle because of the possible danger of shearing.
- Use only smooth-edged atraumatic clamps or forceps.
- After use, this product may be a potential biohazard. Handle and discard in accordance with accepted medical practice.
- Prompt removal of the catheter is advised after infusion is complete to reduce risk of infection.
- The bolus component is equipped with a rapid priming mechanism. See PRIMING THE BOLUS COMPONENT for directions for use.

WARNINGS

- Assure that the catheter is not in a vein or artery. Even if aspirations for blood are negative, intravascular penetration is still possible. Visual inspection, test dosing and patient monitoring are recommended - refer to the drug manufacturer's package insert.
- Do not suture catheter.

CONTRAINDICATIONS

- The ON-Q Soaker is not intended for intravenous, intra-arterial or epidural drug delivery.
- The ON-Q Soaker is not intended for the delivery of blood, blood products, lipids or fat emulsions.

SUGGESTED CATHETER MAINTENANCE

The catheter should be maintained in accordance with standard hospital protocols.

DIRECTIONS FOR USE

Use Aseptic Technique

FILLING THE ON-Q PUMP

Figure 2

- Close clamp on tubing.
- Un-cap the fill port. Do not discard cap.
- Attach filled syringe to the fill port and inject fluid into pump. Repeat as necessary.
- Do not exceed maximum fill volume (see Table 1).
- Replace fill port cap.
- Label with the appropriate pharmaceutical and patient information.

PRIMING THE BOLUS COMPONENT AND TUBING

- The pump is packaged in the priming position with the red priming tab in place.
- **CAUTION**: Do not remove the red priming tab until the tubing is completely primed. Place the bolus component on a flat surface with the red tab label side up.
- Press the bolus button until it latches. Open the tubing clamp and remove the distal end cap to prime the tubing (up to 15 minutes). Allow the medication to fill the entire tubing and luer connector.
- When all air has been removed from the tubing and connector, remove the red priming tab by pulling straight out. The plunger on the bolus component will return to its upper most position allowing the bolus chamber to fill. The pump is now ready for use. Close the clamp until ready to use.

PRIMING THE CATHETER

Figure 3

1. Proper priming of the catheter and pump tubing is very important. Any trapped air in the catheter may create air locks which may affect proper catheter performance.
2. Attach a syringe filled with medication to the catheter connector. Slowly prime the catheter until medication infuses out all the holes along the length of the catheter. Make sure no air is trapped in the catheter.

PLACING THE CATHETER

Figure 4

1. Remove needle guard from the introducer while holding T-handle ❶.
   Do not apply excessive pressure to the T-handle.
   Grip only the needle hub ❷ during insertion.
2. Insert introducer needle (with bevel up) through the skin (approximately 3-5 cm away from wound site) then push introducer needle into the surgical wound site.

Figure 5

3. While holding the T-handle, withdraw the introducer needle ❶.

Figure 6

4. Insert the marked end of the catheter through the opening of the T-handle introducer into the wound site.

WARNINGS

- Assure that the catheter tip is not in a vein or artery. Do not suture catheter.

NOTE
- Catheter placement will vary depending on surgical procedure. Care should be taken during catheter placement to ensure that occlusion will not occur during use and that catheter removal will not be impeded.

Figure 7
5. Drug infusion occurs between catheter marking and marked tip (see Table 2).

Figure 8
6. Advance catheter into wound site until entire catheter segment is visible.
7. While holding catheter tip ❶ withdraw T-handle from puncture site ❷ and split the introducer sheath and peel it away from the catheter ❸.
8. Place the catheter within wound site to desired position. Ensure that entire infusion segment is within wound site.

WARNINGS
- Assure that the catheter is not in a vein or artery. Even if aspirations for blood are negative, intravascular penetration is still possible. Visual inspection, test dosing and patient monitoring are recommended - refer to the drug manufacturer's package insert.

Figure 9
9. Attach syringe to catheter connector and prime catheter with local anesthetic.

Figure 10
10. Attach the catheter connector to the pump tubing. Do not introduce air while connecting. Open the tubing clamp to begin infusion.

Figure 11
11. Secure catheter by coiling close to the insertion site.
12. Apply occlusive dressing (not included) over insertion site and coiled catheter, keeping separate from wound site. Do not cover filter.
13. NOTE: The bolus compoent should not be in contact with cold therapy pads.

NOTE
- The ON-Q system may contain an E-Clip and/or Carry Case. If using the E-Clip, attach to the top of the pump. Secure the ON-Q pump with the E-Clip or Carry Case.
- Infusion is complete when the ON-Q pump is no longer inflated.

REMOVING THE CATHETER

CAUTION
- The catheter should be easy to remove. If significant resistance is felt, then it is advisable to wait 30 to 60 minutes and try again. The patient's body movements may relieve the catheter to allow easier removal. Check the distal end of the catheter for black marking to ensure the entire catheter was removed.

Delivery Time Information for the ON-Q Post-Op Pain Relief Systems

Table 1

PRODUCT INFORMATION									
Models		100 - 023002	270 - 023002	100 - 053002	270 - 053002	270 - 056005	400 - 056005	270 - 053000	400 - 106000
Nominal Bolus Volume (ml)		2	2	5	5	5	5	5	10
Nominal Refill Time (min)		30	30	30	30	60	60	30	60
Nominal Basal Flow Rate (ml/hr)		2	2	2	2	5	5	--	--
Maximum Delivery (ml/hr)		6	6	12	12	10	10	10	10
Nominal Fill Volume (ml)		100	270	100	270	270	400	270	400
Maximum Fill Volume (ml)		125	335	125	335	335	500	335	500
Retained Volume (ml)		≤ 4	≤ 9	≤ 4	≤ 9	≤ 9	≤ 15	≤ 9	≤ 15
Approximate Basal Only Delivery Time*		Fill Volume (ml)							
12 hours	0.5 day	35		35			95		
18 hours	0.75 day	50		50					
24 hours	1 day	65		65		150	170		
36 hours	1.5 day						225		
48 hours	2 days	100		100		255	270		
60 hours	2.5 days	125		125		290	310		
72 hours	3 days		175		175	330	350		
84 hours	3.5 days						395		
96 hours	4 days		215		215		440		
120 hours	5 days		250		250				

When filled to nominal volume, delivery accuracy is ±15% (at a 95% confidence interval) of the labeled infusion rate when delivering normal saline at 72° F (21°C).

***CAUTION**: Delivery time will be less for each bolus delivered.

Table 2

	Soaker Catheter 6.5		Soaker Catheter 12.5	
20 GA	Centimeters	Inches	Centimeters	Inches
Infusion Segment	6.5	2.5	12.5	5.0

Dimensions are approximate. Catheter is radiopaque.

CAUTIONS

1. The nominal basal infusion rate and fill volume for each ON-Q pump is labeled on the fill port.
2. Actual infusion and refill times may vary due to:
   - viscosity and/or drug concentration.
   - positioning the ON-Q pump above (time decreases) or below (time increases) the catheter site.
   - temperature: the ON-Q with Bolus is calibrated at room temperature (72°F/21°C). Temperature will affect solution viscosity, resulting in shorter or longer delivery time.
   - Filling the pump less than nominal results in faster flow rate.
   - Filling the pump greater than nominal results in slower flow rate.
3. This product uses DEHP plasticized PVC. Certain solutions may be incompatible with the PVC material used in the administration set. Consult the drug package insert and other available sources of information for a more thorough understanding of possible incompatibility problems.

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

For Customer Service please call:

(800) 448-3569

(949) 206-2700

www.i-flowcorp.com

www.AskYourSurgeon.com

Appendix D
Predicate Regulatory Documentation

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

Database Updated 9/6/2002

Product Classification Database

Device	PUMP, INFUSION, PCA
Medical Specialty	General Hospital
Product Code	MEA
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 AMERICA, INC.
- TUV RHEINLAND OF NORTH AMERICA, INC.
- UNDERWRITERS LABORATORIES, INC.

Database Updated 9/6/2002

[Code of Federal Regulations]
[Title 21, Volume 8]
[Revised as of April 1, 2002]
From the U.S. Government Printing Office via GPO Access
[CITE: 21CFR880.5725]

[Page 392]

TITLE 21--FOOD AND DRUGS

CHAPTER I--FOOD AND DRUG ADMINISTRATION, DEPARTMENT OF HEALTH AND HUMAN
SERVICES (CONTINUED)

PART 880--GENERAL HOSPITAL AND PERSONAL USE DEVICES--Table of Contents

Subpart F--General Hospital and Personal Use Therapeutic Devices

Sec. 880.5725 Infusion pump.

(a) Identification. An infusion pump is a device used in a health care facility to pump fluids into a patient in a controlled manner. The device may use a piston pump, a roller pump, or a peristaltic pump and may be powered electrically or mechanically. The device may also operate using a constant force to propel the fluid through a narrow tube which determines the flow rate. The device may include means to detect a fault condition, such as air in, or blockage of, the infusion line and to activate an alarm.

(b) Classification. Class II (performance standards).

Database Updated April 1, 2002

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 Elastomeric Pump

Common Name: Infusion Pump and Administration Set

Classification Name: Pump, Infusion

Existing Device: I-Flow Elastomeric Pump (K932740, K944692, K984502, K991513, K992072, and K020660 (pending)).

Device Description: The I-Flow Elastomeric Pump consists of an elastomeric pressure source with an integrated administration line. This special 510(k) proposes a change from latex to polyisoprene for the outer bladder. The outer bladder is not in contact with the fluid path and thus does not require biocompatibility. The inner bladder will remain the same and thus drug compatibility will not be affected.

Technology Comparison: There is no change in technology. The latex and polyisoprene bladder are two different types of elastomers with similar properties.

Conclusion: The I-Flow Elastomeric Pump with polyisoprene bladder is substantially equivalent to the existing I-Flow Elastomeric Pump with latex bladder.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 2 6 2002

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

Re: K020862
Trade/Device Name: I-Flow Elastomeric Pump
Regulation Number: 880.5725
Regulation Name: Infusion Pump
Regulatory Class: II
Product Code: MEB
Dated: March 15, 2002
Received: March 18, 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

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

Enclosure

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

Indications For Use:

1. The I-Flow 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 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)

Patricia Cinciotti

(Division Sign-Off)
Division of Dental, Infection Control,
General Hospital Devices
Number 4020862

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

SEP 15 1999

K992072

SUMMARY OF SAFETY AND EFFECTIVENESS

June 17, 1999

Trade Name: Bolus Accessory Set

Common Name: Bolus Accessory

Classification Name: Set, Administration, Intravascular

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

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

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

Telephone: 949.206.2700
Fax: 949.206.2600

1.0 GENERAL INFORMATION

1.1 Purpose of Submission

1.1.1 This submission is intended to notify the Federal Food and Drug Administration that I-Flow Corporation intends to market a new administration set called the Bolus Accessory Set, hereafter identified as the Bolus Accessory.

1.1.2 Trade Name: Bolus Accessory Set
1.1.3 Common Name: Bolus Accessory
1.1.4 Classification Name: Set, Administration, Intravascular
1.1.5 Product Code: 80 FPA
1.1.6 Device Classification: Class II, 880.5440
1.1.7 Classification Panel: General Hospital and Personal Use Device

1.2 Statement of Equivalence

1.2.1 The Bolus Accessory is substantially equivalent to the I-Flow Paragon Bolus Accessory Set (K984638), the Patient Control Module (K884505) marketed by Baxter Healthcare Corporation and the I-Flow Bolus Dispenser (K935811).

2.0 PHYSICAL SPECIFICATIONS AND DESCRIPTIONS

2.1 Description of the Bolus Accessory

2.1.1 The Bolus Accessory may connect to any positive pressure, continuous flow rate infusion pump with an 8 to 17 psi pressure source to deliver fixed boluses of medication upon demand by the patient or healthcare provider.

2.1.2 The Bolus Accessory consists of plastic housing, medication reservoir, bolus button activator and wrist bands.

2.1.3 The bolus button allows patient controlled administration of medication as needed.

2.2 Product Configuration

2.2.1 The Bolus Accessory is available in 0.5 ml bolus volume.

2.3 Components and Materials

2.3.1 All fluid path components of the Bolus Accessory are in conformance with ISO 10993 Part 1.

2.4 Power Requirements

2.4.1 The Bolus Accessory is a mechanical device that requires no external power to operate.

3.0 OPERATIONAL SPECIFICATIONS AND DESCRIPTIONS

3.1 Standard Operating Conditions:

Bolus Volume:	0.5 ml
Refill Time:	variable, determined by pressure source flow rate
Priming/Residual Volume:	<= 0.75 ml
Operating Temperature:	88 ± 2°F (skin temperature)

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Test Solution:	normal saline (0.9% NaCl)
Operating Pressure:	8 to 17 psi pressure source
Head Height:	0"
Accuracy:	bolus volume: ±10% at 95% confidence interval at the identified refill times.

3.2 **Performance Data:** Testing occurred at standard operating conditions. All models performed within the specified accuracy when tested at nominal conditions.

3.3 **Safety/Alarm Functions**

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

3.3.2 The non-linear refill adds additional patient safety if the bolus button is pressed prior to the refill time.

4.0 BIOLOGICAL SPECIFICATIONS

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

5.0 CHEMICAL AND DRUG SPECIFICATIONS

5.1 Compatibility

5.1.1 There are no specific drugs referenced in the labeling for the Bolus Accessory.

5.1.2 The Bolus Accessory is intended for general purpose drugs and pain medication.

6.0 INTENDED USE

6.1 The Bolus Accessory, 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, percutaneous and intra-operative.

6.2 The Bolus Accessory is not intended for continuous delivery.

6.3 The Bolus Accessory is single patient use only.

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

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

7.0 STANDARDS

7.1 There are currently no standards established for mechanical PCA infusion devices.

8.0 PACKAGING

8.1 Packaging is suitable for radiation or ETO sterilization.

9.0 STERILIZATION

9.1 The method of sterilization is gamma radiation (cobalt 60).

10.0 COMPARISON TO LEGALLY MARKETED DEVICES

10.1 The Bolus Accessory is identical to the I-Flow Paragon Bolus Accessory Set with the exception of the source pressure specification. The Bolus Accessory has the same intended use as the following predicate devices: the I-Flow Paragon Bolus Accessory Set, the Baxter Patient Control Module and the I-Flow Bolus Dispenser. The Bolus Accessory has similar bolus volumes and refill times as its predicate device.

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

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

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 ~~(surface/body cavity)~~ and percutaneous.

(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)

Appendix E
Summary of Safety and Effectiveness

SPECIAL 510(K) - SUMMARY OF SAFETY AND EFFECTIVENESS

October 3, 2002

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

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

Trade Names: ON-Q, PainBuster, C-bloc, Eclipse, C-Series, Easypump, Homepump

Classification Name: Pump, Infusion, Elastomeric

Existing Device: I-Flow Elastomeric Pump (K020862)

Device Description: This special 510(k) proposes a new optional component for the I-Flow Elastomeric Pump that incorporates a bolus component. The bolus component offers the additional ability to deliver fixed bolus volumes of medication at fixed time intervals instead of just a continuous infusion rate.

Technology Comparison: The new Bolus Component utilizes the same technology for dispensing medication as the existing unmodified design.

Conclusion: The I-Flow Elastomeric Pump with Bolus is substantially equivalent to the existing I-Flow Elastomeric Pump.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Food and Drug Administration

October 10, 02

Memorandum

From: Reviewer(s) - Name(s) Pandu R. Soprey

Subject: 510(k) Number K023318

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 days

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

MEB II 80 CFR 880.5725

Review: [signature] HFZ-454 Oct 17, 2002
(Branch Chief) (Branch Code) (Date)

Final Review: [signature] 10/18/02
(Division Director) (Date)

Revised:8/17//99

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SPECIAL 510(k): Device Modification
ODE Review Memorandum

To: THE FILE **RE:** DOCUMENT NUMBER **K023318**

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.)

   I-Flow Elastomeric Pump is intended for continuous and or intermittent infusion of medications. The device was cleared under K020862 for I-Flow Elastomeric Pump and K992072 for Bolus accessory Set.

   The device is classified as Class II, 21 CFR Part 880.5725, Product Code 80 MEB

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.

   (b)(4), (b)(5)

   (b)(4), (b)(5)

   No other changes are made to the pump specifications, indications, intended use, sterilization, packaging or labeling.

   There are no changes in the labeling.

   The Indications for Use statement is provided in page 4.

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**.

   (b)(4), (b)(5)

   (b)(4), (b)(5)

4. **Comparison Information** (similarities and differences) to applicant's legally marketed predicate device including, labeling, intended use, physical characteristics, and

   Detail description and comparison is provided in pages 10.

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.

Declaration of Conformity is provided on page 5
Risk analysis is provided in Appendix A

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.

Truthful and Accurate Statement is provided in Page 3
The Indications for Use statement is provided in is provided in Page 4
510(k) Summary is provided in Appendix E
There are no changes in the labeling.

James R. Sluel

(Reviewer's Signature)

Oct 16, 02

(Date)

Comments

Non Sterile 10/17/02

The modified device is SE to the predicate I-Flow Elastomeric Pump cleared under K992072

Revised:3/27/98

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

510(k) Number: K023318

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.

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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) 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.

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 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: [signature] Oct 10, 02

Concurrence by Review Branch: ____

Date: OCT - 7 [illegible]

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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