



USER: GRAY, ILKA K (ixg)

FOLDER: K992072 - 81 pages (FOI:08007474)

COMPANY: I-FLOW CORP. (IFLOW)

PRODUCT: SET, ADMINISTRATION, INTRAVASCULAR
(FPA)

SUMMARY: Product: BOLUS ACCESSORY SET

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

DATE PRINTED: Tue Nov 23 16:56:40 2010

Note: Releasable Version

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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: $88 \pm 2^{\circ}\text{F}$ (skin temperature)

Test Solution: normal saline (0.9% NaCl)
Operating Pressure: 8 to 17 psi pressure source
Head Height: 0"
Accuracy: bolus volume: $\pm 10\%$ 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.



SEP 15 1999

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

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 (Pre-market 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

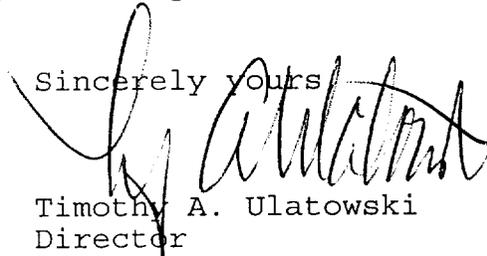
Page 2 -Mr. Fry

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 (~~artificial body cavity~~) and percutaneous.

Palma Curvite

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

510(k) Number 1992072

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓
(Per 21 CFR 801.109)

OR

Over-The-Counter Use _____

(Optional Format 1-2-96)



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

SEP 15 1999

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

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

Re: K992072
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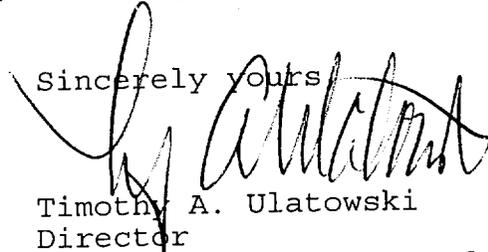
Page 2 -Mr. Fry

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Sincerely yours



Timothy A. Ulatowski
Director
Division of Dental, Infection Control,
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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 (~~percutaneous (body cavity)~~) and percutaneous.

Adrian Cuente

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

510(k) Number 1992072

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use
(Per 21 CFR 801.109)

OR

Over-The-Counter Use _____

(Optional Format 1-2-96)

From: Reviewer(s) - Name(s) HUNG TRINH

Subject: 510(k) Number K992072

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

- Refused to accept.
- Requires additional information (other than refuse to accept).
- Accepted for review _____.
- 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 YES NO

This 510(k) contains:

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

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

The required certification and summary for class III devices

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

Material of Biological Origin YES NO

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

- No Confidentiality
- Confidentiality for 90 days
- Continued Confidentiality exceeding 90 days

Predicate Product Code with class:

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

80 FPA Class II

Review: Patricia Cicento
(Branch Chief)

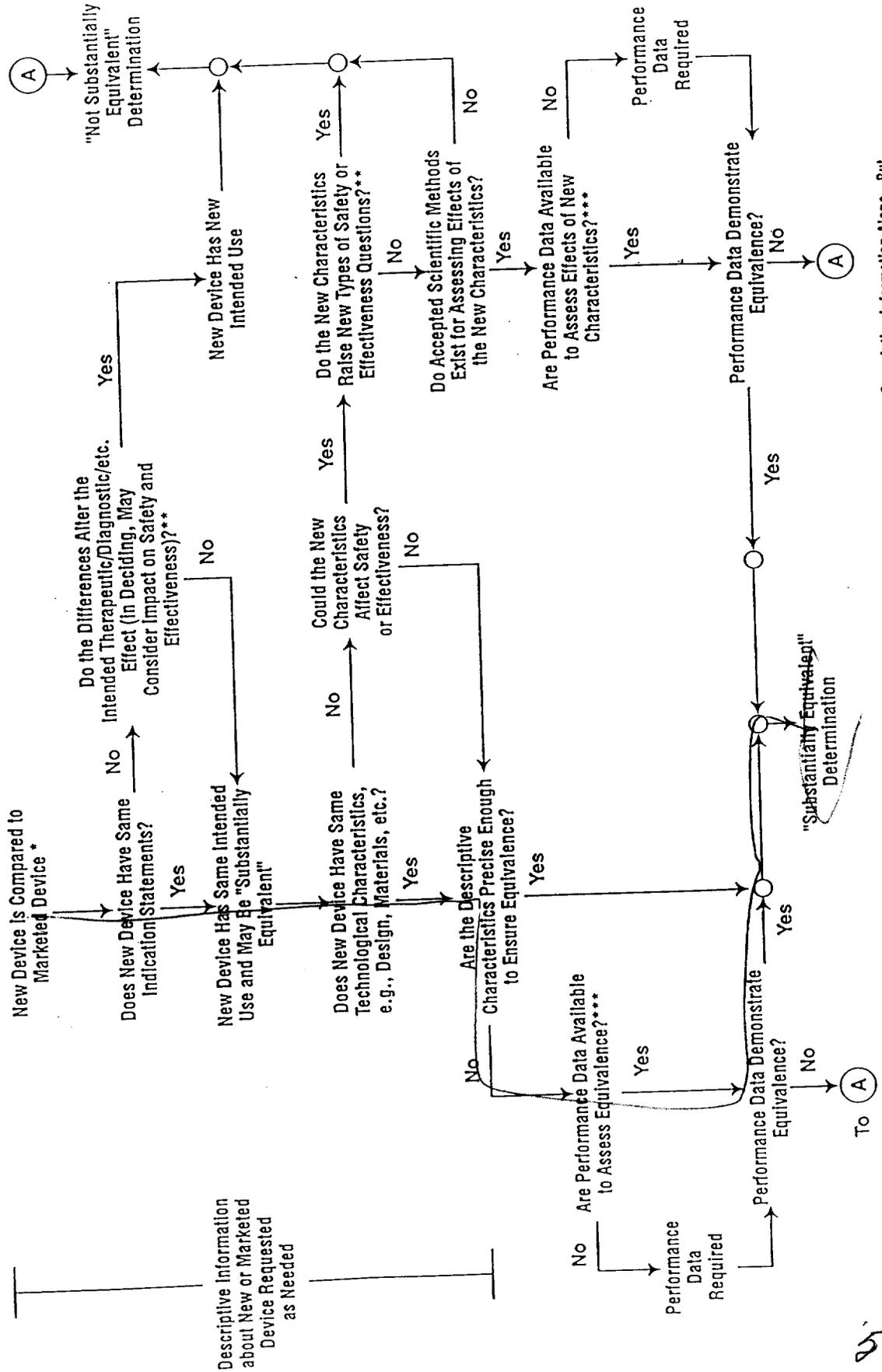
CGHDB
(Branch Code)

9/15/99
(Date)

Final Review: _____
(Division Director)

9/15/99
(Date)

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



* This information is normally based on descriptive information alone, but additional information is sometimes required.

** This information is limited to the 510(k), other 510(k)s, the Center's Classification Files, or the Literature.

*** Data

Compare New Devices to Marketed Devices. FDA Requests Information on the Relationship Between Marketed and "Predicate" (Pre-Amendment or Reclassified Post-Amendment) Devices is Unclear.

**MEMO TO THE RECORD
510(K) REVIEW**

DATE: 9/9/99
FROM: Hung Trinh
DOCUMENT: K992072
COMPANY NAME: I-Flow Corp
DEVICE NAME: Bolus Accessory Set

OFFICE: HFZ-480
DIVISION: DDIG/GHDB

Contact point: Stan Fry, VC Regulatory and Legal Affairs
949-206-2700
949-206-2600 (fx)

NARRATIVE DEVICE DESCRIPTION

1. **SUMMARY DESCRIPTION OF THE SUBMISSION UNDER REVIEW:**
The firm intends to market a new administration set that is identical to the Paragon Bolus accessory set (K984638) with the exception of the source operating pressure.
2. **INTENDED USE:**
The device is intended to provide a continuous basal level infusion of medication and to allow patient controlled bolus delivery.
3. **DEVICE DESCRIPTION:**
 - A. **Life-supporting or life-sustaining:** no
 - B. **Implant (short-term or long-term):** no
 - C. **Is the device sterile?** yes
If yes, is sterility information provided? yes
Gamma radiation (cobalt 60) or ETO gas. Gamma radiation validation methodology is by ANSI/AAMI ST32-1191/EN 552; dosage from (b)(4) to (b)(4) kGy. ETO sterilization complies with ANSI/AAMI/ISO 11135-1994/EN550
 - D. **Is the device for single use?** Single patient use
 - E. **Is the device for prescription use?** yes
If yes, is prescription labeling included? yes
 - F. **Is the device for home use or portable?** yes
 - G. **Does the device contain drug or biological product as a component?** no
 - H. **Is this device a kit?** no
 - I. **Software-driven:** no
 - J. **Electrically Operated:** no
 - K. **Applicable standards to which conformance has been demonstrated (e.g., IEC, ANSI, ASTM, etc.):** no
 - L. **Device(s) to which equivalence is claimed, manufacturer, and 510(k) number or preamendment status:**
Baxter Basal/Bolus Infusor (K884505)
I-Flow Bolus Dispenser (K935811)
Paragon Bolus accessory set (K984638)
 - M. **Submission provides comparative specifications**

	yes
comparative in vitro data	no
performance data	yes
animal testing	no

clinical testing no
biocompatibility testing no (same material as predicate)

N. 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. Provide a summary about the devices design, materials, physical properties and toxicology profile if important.

The device is identical to the Paragon Bolus accessory set (K984638) with the exception of the source operating pressure. It is designed operate with any positive pressure, continuous flow rate infusion pump with an 8 to 17 pressure source to deliver fixed boluses of medication upon demand by the patient or healthcare provider. It consists of a plastic housing, bolus button activator, and wristband. The input and output of the device is connected to the accessories via male and female luer locks.

This device **does not** deliver continuous medication. The refill time of the medication reservoir is determined by the flow control orifice of the administration set, and therefore, is inversely proportional to the flow rate:

$$\frac{(b)(4)}{(b)(4)} = \text{refill time (min)}$$

The Baxter Patient Control module is very similar to the subject device in that it is composed of a plastic housing, medication reservoir, bolus button activator, and wrist bands. It also requires a pressure source to fill the medication reservoir.

Comparative specs:

Comparison Element	Paragon Bolus Accessory Set	Baxter Patient Control Module	Bolus Accessory set
Bolus Volume	0.5 ml; +10% @ 95% confidence interval	0.5 ml	0.5 ml; +10% @ 95% confidence interval
Bolus Lockout time	3.6, 9, 18, 35 and 70 min; +15% @ 95% confidence interval	6, 15, 60 min	3.6, 9, 18, 35 and 70 min; +15% @ 95% confidence interval
Pump Volume	100 ml	65 ml	Pump dependent
Pressure source	Mechanical spring energy of the pump	Strain energy of elastomeric membranes	Mechanical Spring
Fluid Reservoir	PVC drug bag	Elastomeric membrane	N/A

Test results show that the device does operate within specifications.

O. Does the submission include a summary of safety and effectiveness information upon which an equivalence determination is based? yes

P. RECOMMENDATION:

I believe that this device is equivalent to: 80 FPA

Classification should be based on:

880.5440 Intravascular (IV) administration set **Class: II**

If the device is substantially equivalent to a class III device, does the submission include: (1) certification that a reasonable search of all information known, or otherwise available, about the generic type of device has been performed and (2) a summary description of the types of safety and effectiveness problems associated with the type of device and a citation to the literature, or other sources of information, upon which they have based the description? n/a

HT 9/14/99

"SUBSTANTIAL EQUIVALENCE" (SE) DECISION MAKING DOCUMENTATION

K992072

Reviewer: Hung Trinh

Division/Branch: DDIGD/GHDB

Device Name: Bolus Accessory set

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

YES NO

1.	Is Product A Device	X		If NO = Stop
2.	Is Device Subject To 510(k)?	X		If NO = Stop
3.	Same Indication Statement?	X		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?	X		If YES = Go To 7
6.	Could The New Characteristics Affect Safety Or Effectiveness?			If YES = Go To 8
7.	Descriptive Characteristics Precise Enough?		X	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?	X		If NO = Request Data
11.	Data Demonstrate Equivalence?	X		Final Decision: SE

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.

9



I-FLOW CORPORATION

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

September 14, 1999

VIA FACSIMILE: (301)480-3002

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

Attn: Mr. Hung Trinh

Re 510(k) Number: **K992072**
Received: **19-JUN - 1999**
Product: **BOLUS ACCESSORY SET**

Dear Mr. Trinh:

This letter will confirm our conversation on the above referenced matter wherein I-Flow Corporation agrees to amend the Indications for Use product. Specifically, the parenthetical statement, *(soft tissue/body cavity)*, is removed from the submitted indications and will not be used in our labeling on the product.

I also take this opportunity to confirm that I am the Official Correspondent for I-Flow Corporation and I am authorized to speak for the corporation on this matter.

Sincerely,

STANLEY E. FRY
Vice President, Regulatory Affairs and
Quality Assurance

Screening Checklist

For all Premarket Notification 510(k) Submissions

Device Name: <u>Bdms coronary pet</u>						K 99 2072						
Submitter (Company): <u>el flow corp</u>												
Items which should be included (circle missing & needed information)						SPECIAL		ABBREVIATED		TRADITIONAL		✓ IF ITEM IS NEEDED AND IS MISSING
						YES	NO	YES	NO	YES	NO	
1. Cover Letter clearly identifies Submission as: a) "Special 510(k): Device Modification" b) "Abbreviated 510(k)" c) Traditional 510(k)						GO TO # 2,3		GO TO # 2,4,5		GO TO # 4,5		
✓ IF ITEM IS NEEDED												
2. GENERAL INFORMATION: REQUIRED IN ALL 510(K) SUBMISSIONS												
Financial Certification or Disclosure Statement for 510(k)s with a Clinical Study 807.87(i)						NA		YES		NO		AND IS MISSING
						SPECIALS		ABBREVIATED		TRADITIONAL		
						YES	NO	YES	NO	YES	NO	
a) trade name, classification name, establishment registration number, device class												
b) OR a statement that the device is not yet classified						FDA-may be a classification request; see coordinator						
c) identification of legally marketed equivalent device						NA						
d) compliance with Section 514 - performance standards						NA						
e) address of manufacturer												
f) Truthful and Accurate Statement												
g) Indications for Use enclosure												
h) SMDA Summary or Statement (FOR ALL DEVICE CLASSES)												
i) Class III Certification & Summary (FOR ALL CLASS III DEVICES)												
j) Description of device (or modification) including diagrams, engineering drawings, photographs, service manuals												
k) Proposed Labeling:												
i) package labeling (user info)												
ii) statement of intended use												
iii) advertisements or promotional materials												
i) MRI compatibility (if claimed)												
l) Comparison Information (similarities and differences) to named legally marketed equivalent device (table preferred) should include:												
i) Labeling												
ii) intended use												
iii) physical characteristics												
iv) anatomical sites of use												
v) performance (bench, animal, clinical) testing						NA						
vi) safety characteristics						NA						
m) If kit, kit certification												
3. "SPECIALS" - ONLY FOR MODIFICATIONS TO MANUFACTURER'S OWN CLASS II, III OR RESERVED CLASS I DEVICE												
a) Name & 510(k) number of legally marketed (unmodified) predicate device												
b) STATEMENT - INTENDED USE AND INDICATIONS FOR								* If no - STOP not a special				

USE OF MODIFIED DEVICE AS DESCRIBED IN ITS LABELING HAVE NOT CHANGED*				
c) STATEMENT - FUNDAMENTAL SCIENTIFIC TECHNOLOGY OF THE MODIFIED DEVICE HAS NOT CHANGED*				* If no - STOP not a special
d) Design Control Activities Summary				
i) 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				
ii) 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				
iii) A declaration of conformity with design controls. The declaration of conformity should include:				
1) 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				
2) A statement signed by the individual responsible, that manufacturing facility is in conformance with design control procedure Requirements as specified in 21 CFR 820.30 and the records are available for review.				

	SPECIALS		ABBREVIATED		TRADITIONAL		✓ IF ITEM IS NEEDED AND IS MISSING
	YES	NO	YES	NO	YES	NO	
4. ABBREVIATED 510(K): SPECIAL CONTROLS/CONFORMANCE TO RECOGNIZED STANDARDS - PLEASE FILL OUT THE STANDARDS ABBREVIATED FORM ON THE H DRIVE							
a) 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							
b) If a manufacturer elects to use an alternate approach to address a particular risk, sufficient detail should be provided to justify that approach.							
c) For a submission, which relies on a recognized standard, a declaration of conformity to the standard. The declaration should include the following:							
i) An identification of the applicable recognized consensus standards that were met							
ii) A specification, for each consensus standard, that all requirements were met, except for							

inapplicable requirements or deviations noted below		
iii) An identification, for each consensus standard, of any way(s) in which the standard may have been adapted for application to the device under review, e.g., an identification of an alternative series of tests that were performed		
iv) An identification, for each consensus standard, of any requirements that were not applicable to the device		
v) A specification of any deviations from each applicable standard that were applied		
vi) A specification of the differences that may exist, if any, between the tested device and the device to be marketed and a justification of the test results in these areas of difference		
vii) Name/address of test laboratory/certification body involved in determining the conformance of the device with applicable consensus standards and a reference to any accreditations for those organizations		
d) Data/information to address issues not covered by guidance documents, special controls, and/or recognized standards		

5. Additional Considerations: (may be covered by Design Controls)									
a) Biocompatibility data for all patient-contacting materials, OR certification of identical material/formulation:									
i) component & material									
ii) identify patient-contacting materials									
iii) biocompatibility of final sterilized product									
b) Sterilization and expiration dating information:									
i) sterilization method									
ii) SAL									
iii) packaging									
iv) specify pyrogen free									
v) ETO residues									
vi) radiation dose									
c) Software validation & verification:									
i) hazard analysis									
ii) level of concern									
iii) development documentation									
iv) certification									

Items shaded under "NO" are necessary for that type of submission. Circled items and items with checks in the "Needed & Missing" column must be submitted before acceptance of the document.

Passed Screening Yes No Reviewer: MAS
 Date: 6/22/97 Concurrence by Review Branch: _____

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

	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 for home use 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 #I91-2 and Federal Register 90N0332, September 10, 1991.		

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

June 21, 1999

I-FLOW CORP.
20202 WINDROW DR.
LAKE FOREST, CA 92630
ATTN: ROBERT J. BARD

510(k) Number: K992072
Received: 19-JUN-1999
Product: BOLUS ACCESSORY SET

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.**

On January 1, 1996, FDA began requiring that all 510(k) submitters provide on a separate page and clearly marked "Indication For Use" the indication for use of their device. If you have not included this information on a separate page in your submission, please complete the attached and amend your 510(k) as soon as possible. Also if you have not included your 510(k) Summary or 510(k) Statement, or your Truthful and Accurate Statement, please do so as soon as possible. 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 Assistance (DSMA) 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 (HFZ-401) at the above letterhead address. Correspondence sent to any address other than the Document Mail Center will not be considered as part of your official premarket notification submission. Because of equipment and personnel limitations, we cannot accept telefaxed material as part of your official premarket notification submission, unless specifically requested of you by an FDA official. Any telefaxed material must be followed by a hard copy to the Document Mail Center (HFZ-401).

You should be familiar with the manual entitled, "Premarket Notification 510(k) Regulatory Requirements for Medical Devices" available from DSMA. 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 DSMA 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

K992072

CENTER FOR DEVICES AND RADIOLOGICAL HEALTH
Premarket Submission Cover Sheet

Date of Submission: _____ FDA Document Number: _____

Section A Type of Submission

- 510(k)
- 510(k) Add'l information
- IDE
- IDE Amendment
- IDE Supplement
- IDE Report
- PMA
- PMA Amendment
- PMA Report
- PMA Supplement - Regular
- PMA Supplement - Special
- PMA Supplement - 30 day
- PMA Supplement - Panel Track

Section B1 Reason for Submission — 510(k)s Only

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

Section B2 Reason for Submission — PMAs Only

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

Section B3 Reason for Submission — IDEs Only

- New device
- Addition of institution
- Expansion / extension of study
- IRB certification
- Request hearing
- Request waiver
- Termination of study
- Withdrawal of application
- Unanticipated adverse effect
- Emergency use:
 - Notification of emergency use
 - Additional information
- Other reason (specify): _____
- Change in:
 - Correspondent
 - Design
 - Informed consent
 - Manufacturer
 - Manufacturing
 - 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
- IOL submissions only:
 - Change in IOL style
 - Request for protocol waiver

5/19

18

40/11

Section C

Product Classification

Product code: 80 FPA	C.F.R. Section: 80.5440	Device class: <input type="checkbox"/> Class I <input type="checkbox"/> Class III <input checked="" type="checkbox"/> Class II <input type="checkbox"/> Unclassified
Classification panel: General Hospital and Personal Use Device		

Section D

Information on 510(k) Submissions

Product codes of devices to which substantial equivalence is claimed:				Summary of, or statement concerning, safety and effectiveness data: <input checked="" type="checkbox"/> 510(k) summary attached <input type="checkbox"/> 510(k) statement
1 80 FPA	2 80 FRN	3	4	
5	6	7	8	

Information on devices to which substantial equivalence is claimed:

510(k) Number	Trade or proprietary or model name	Manufacturer
1 K984638	1 Paragon Bolus Accessory Set	1 I-Flow Corp.
2 K884505	2 Patient Control Module	2 Baxter Healthcare Corp.
3 K935811	3 Bolus Dispenser	3 I-Flow Corp.
4	4	4
5	5	5
6	8	8

Section E

Product Information — Applicable to All Applications

Common or usual name or classification name:

Bolus Accessory Set

Trade or proprietary or model name	Model number
1 Bolus Accessory Set	1
2	2
3	3
4	4
5	5
6	6

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

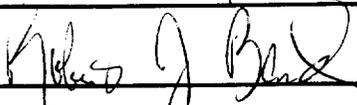
1	2	3	4	5	6
7	8	9	10	11	12

Data included in submission: Laboratory testing Animal trials Human trials

Indications (from labeling): 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, percutaneous and intra-operative (soft tissue / body cavity).

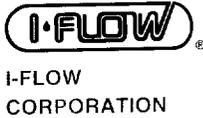
				FDA Document Number:			
Section F Manufacturing / Packaging / Sterilization Sites							
<input checked="" type="checkbox"/> Original <input type="checkbox"/> Add <input type="checkbox"/> Delete		FDA establishment registration number: 2026095		<input checked="" type="checkbox"/> Manufacturer <input type="checkbox"/> Contract manufacturer		<input type="checkbox"/> Contract sterilizer <input type="checkbox"/> Repackager / relabeler	
Company / Institution name: I-Flow Corporation							
Division name (if applicable):				Phone number (include area code):			
				(949) 206-2700 ext. 2670			
Street address:				FAX number (include area code):			
20202 Windrow Drive				(949) 206-2603			
City: Lake Forest		State / Province: CA		Country: U.S.A.		ZIP / Postal Code: 92630	
Contact name: Robert J. Bard, Esq., R.A.C.							
Contact title: Vice President of Regulatory and Legal Affairs							
<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:							
Division name (if applicable):				Phone number (include area code):			
				()			
Street address:				FAX number (include area code):			
				()			
City:		State / Province:		Country:		ZIP / Postal Code:	
Contact name:							
Contact title:							
<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:							
Division name (if applicable):				Phone number (include area code):			
				()			
Street address:				FAX number (include area code):			
				()			
City:		State / Province:		Country:		ZIP / Postal Code:	
Contact name:							
Contact title:							

20

				FDA Document Number:	
Section G Applicant or Sponsor					
Company / Institution name: I-Flow Corporation				FDA establishment registration number: 2026095	
Division name (if applicable):				Phone number (include area code): (949) 206-2700 ext. 2670	
Street address: 20202 Windrow Drive				FAX number (include area code): (949) 206-2603	
City: Lake Forest	State / Province: CA	Country: U.S.A.	ZIP / Postal Code: 92630		
Signature: 					
Name: Robert J. Bard, Esq., R.A.C.					
Title: Vice President of Regulatory and Legal Affairs					
Section H Submission correspondent (if different from above)					
Company / Institution name:					
Division name (if applicable):				Phone number (include area code): ()	
Street address:				FAX number (include area code): ()	
City:	State / Province:	Country:	ZIP / Postal Code:		
Contact name:					
Contact title:					

Your voluntary completion of this Premarket Submission Cover Sheet will not affect any FDA decision concerning your submission, but will help FDA's Center for Devices and Radiological Health process your submission more efficiently. The information you provide should apply *only* to a single accompanying submission. Please do not send cover sheets for any previous submissions. See the instructions for additional information on completing the cover sheet. If you have a question concerning completion of the cover sheet, please contact the Division of Small Manufacturers Assistance at (800) 638-2041 or (301) 443-6597.

21



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

Premarket Notification – 510(k)

Via Federal Express
 June 17, 1999

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

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 *Bolus Accessory Set* prior to the introduction into interstate commerce for commercial distribution.

I-Flow intends to market a new administration set called the *Bolus Accessory Set*. The *Bolus Accessory Set* 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).

All questions and/or comments concerning this document should be made to:
 Robert J. Bard, Esq., R.A.C.
 Vice President Regulatory and Legal Affairs

I-Flow Corporation
 20202 Windrow Drive
 Lake Forest, CA 92630
 Telephone: 949.206.2700
 Fax: 949.206.2600

Sincerely,

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

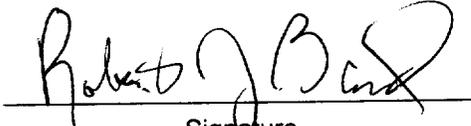
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 FDA/CDRH/ODE/DMC



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

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

I certify that, in my capacity as the Vice President of Regulatory and Legal Affairs of I-Flow Corporation, I believe to the best of my knowledge, that all data and information submitted in the premarket notification for the Bolus Accessory Set are truthful and accurate and that no material fact has been omitted.



 Signature

Robert J Bard, Vice President of Regulatory and Legal Affairs

Name	Title
<u>I-Flow Corporation</u>	<u>6/17/99</u>
Company	Dated

 Premarket Notification (510(k) Number)



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 (~~soft tissue/body cavity~~) and percutaneous.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use _____
(Per 21 CFR 801.109)

OR

Over-The-Counter Use _____

(Optional Format 1-2-96)

TABLE OF CONTENTS

1.0 GENERAL INFORMATION Page 1

2.0 PHYSICAL SPECIFICATIONS AND DESCRIPTION Page 1

3.0 OPERATIONS SPECIFICATIONS AND DESCRIPTION Page 4

4.0 BIOLOGICAL SPECIFICATIONS Page 6

5.0 CHEMICAL AND DRUG SPECIFICATIONS Page 7

6.0 INTENDED USE Page 7

7.0 LABELS AND LABELING Page 7

8.0 STANDARDS Page 8

9.0 PACKAGING Page 8

10.0 STERILIZATION INFORMATION Page 8

11.0 COMPARISON TO LEGALLY MARKETED DEVICES Page 8

Appendix A – Bolus Accessory Set Drawings

Appendix B – Bolus Accessory Set Labeling

Appendix C – Bolus Accessory Set Performance Data

- Chart #1 - Volume (ml) Accuracy 72 min. refill time
- Chart #2 - Volume (ml) Accuracy 18 min. refill time
- Chart #3 - Volume (ml) Accuracy 7.2 min. refill time
- Chart #4 - Volume (ml) Accuracy 3.6 min. refill time
- Chart #5 - Volume (ml) Accuracy Life Test
- Chart #6 - Volume (ml) Accuracy Life Test
- Chart #7 - Refill Time Accuracy Life Test
- Chart #8a - Bolus Accessory Pressure Profile
- Chart #8b - Baxter Patient Control Module Pressure Profile

Appendix D – Predicate Labeling

- I-Flow Paragon Bolus Accessory Set
- Baxter Patient Control Module
- I-Flow Bolus Dispenser

Appendix E – Summary of Safety and Effectiveness

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

See Appendix A for drawings.

- 2.1.1 The Bolus Accessory is identical to the Paragon Bolus Accessory (K984638) with the exception of the source operating pressure.
- 2.1.2 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.
- 2.1.3 The Bolus Accessory consists of plastic housing, medication reservoir, bolus button activator and wrist band.
- 2.1.4 The bolus button allows patient controlled administration of medication as needed.

(b) (4)

(b)(4)

Top View

Side View

2.2 Bolus Refill Cycle (i.e. Refill Time)

- 2.2.1 The infusion pump connected to the Bolus Accessory provides the pressure to push the fluid into the inlet port of the Bolus Accessory.
- 2.2.2 The flow control orifice of the infusion pump establishes a refill period during which the patient cannot receive another full bolus of medication.

2.2.2.1 The time required to fill the bolus cavity is called the “refill time”.

2.2.2.2 Refill times vary according to the flow rate of the infusion pump. The refill time is computed by (b) (4)

(b) (4)

See table below.

Nominal Flow Rate of Pressure Source (ml/hr)	Refill Time	
	(min.)	(sec.)
(b) (4)	(b) (4)	
		(b) (4)

The refill time is approximated as follows:

(b) (4)

- 2.2.3 As fluid flows into the bolus cavity, the diaphragm is continuously displaced until the cavity is full.
 - 2.2.3.1 The bolus cavity is filled non-linearly, slower in the beginning and more rapidly towards the end of the refill cycle. See chart #8a for the pressure profile.
 - 2.2.3.2 The bolus reservoir has a 0.5 ml volume.

2.3 Bolus Activation

- 2.3.1 On the opposite side of the diaphragm is a bolus button. The button moves with the diaphragm as it is displaced.
- 2.3.2 At any time while the bolus cavity is filling, the button can be pressed by the user. Only when the bolus cavity is full will the patient receive the entire bolus.
- 2.3.3 When the button is pressed, the fluid in the bolus cavity is pushed out and forced through a check valve. At this point, the refill cycle begins.

2.4 Product Configuration

Bolus Accessory Model

- 2.4.1 BA00005: 0.5 ml bolus volume.
- 2.4.2 BA00005V: 0.5 ml bolus volume with inlet port check valve.
 - 2.4.2.1 This model is for use with high flow rate (i.e. 50 to 200 ml/hr) infusion pumps. When the bolus button is pressed, the inlet port check valve prevents the bolus reservoir from partially backing up into the set tubing. Low flow rate sets have sufficient restriction to prevent backup when the bolus button is pressed.

2.5 Components and Materials

The Bolus Accessory is a disposable device intended for single patient use. The component materials are identical to the Paragon Bolus Accessory Set (K984638).

2.5.1 Non-fluid path components

- 2.5.1.1 Bolus Button: (b) (4)
- 2.5.1.2 Outer Housing: (b) (4)
- 2.5.1.3 Luer Cap: Polycarbonate, (b) (4)
(b) (4)
- 2.5.1.4 Slide Clamp: (b) (4)
- 2.5.1.5 Wrist Band: (b) (4)

2.5.2 Fluid path components

- 2.5.2.1 Inner Housing: (b) (4)
- 2.5.2.2 Diaphragm: (b) (4)
- 2.5.2.3 Outlet Port Check Valve: (b) (4)
- 2.5.2.4 Luer Adapters: (b) (4)
- 2.5.2.5 Tubing (Make-up): (b) (4)
- 2.5.2.6 Solvent Bonding: (b) (4)
(b) (4)

2.5.2.7 Inlet Port Check Valve (optional): For use with model BA00005V for high flow rate sets (50 to 200 ml/hr). The inlet port check valve may be permanently bonded to the Bolus Accessory or a separate attachable component.

2.5.2.7.1 Housing: (b)(4) (b)(4)
 (b)(4) (b)(4)

2.5.2.7.2 Check Valve: (b)(4) (b)(4)
 (b)(4) (b)(4)

2.6 Power Requirements

2.6.1 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

Nominal Flow Rate of Pressure Source (ml/hr)	Refill Time	
	(min.)	(sec.)
(b)(4)	(b)(4)	
(b)(4)	(b)(4)	
		(b)(4)
		(b)(4)

Priming/Residual Volume: <= 0.75 ml (Bolus Accessory Set)

Operating Temperature: 88 ± 2°F (skin temperature)

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

(b)(4)

(b)(4)

(b) (4)

(b)(4)

3.2.2 Bolus volume accuracy life test:

(b) (4)

(b)(4)

3.2.3 Bolus refill time accuracy life test:

(b) (4)

(b)(4)

(b) (4)

3.2.4

(b)(4)

3.2.5

3.3 Safety/Alarm Functions

- 3.3.1 The Bolus Accessory will not be recommended for any application that exceeds the minimum internal pressure of the system.
- 3.3.2 This device contains no alarms or indicators for flow other than visual.
- 3.3.3 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 All fluid path components in the Bolus Accessory are identical in formulation to materials currently being used in other I-Flow products and have a long history of use in devices used for infusion of fluids.
- 4.2 I-Flow Corporation certifies that to the best of its knowledge that all fluid path materials are exactly the same as in legally marketed devices and the conditions of use are comparable.
- 4.3 Biological testing is in conformance with ISO 10993 Part 1 for all fluid path components. The Bolus Accessory has been tested to and passed the following tests:
 - 4.3.1 Cytotoxicity: In-vitro cytotoxicity testing (MEM elution method using L-929 mouse fibroblast cells)
 - 4.3.2 Sensitization: Guinea pig maximization tests delayed contact sensitization test (maximum method for biomaterial extracts)
 - 4.3.3 Irritation: USP/ISO intracutaneous test
 - 4.3.4 Systemic Toxicity: Acute systemic injection test
 - 4.3.5 Hemolysis: In-vitro rabbit blood determination
 - 4.3.6 Subchronic Toxicity: Subacute toxicity test

- 4.3.7 Implantation: Rabbit implantation test
- 4.3.8 Pyrogenicity: Material mediated pyrogenicity

4.4 The Bolus Accessory is categorized as follows:

- 4.4.1 Device Category: External Communicating Device.
- 4.4.2 Body Contact: Blood Path, Indirect
- 4.4.3 Contact Duration: Prolonged

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.

5.2 Drug Stability

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

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 LABELS AND LABELING

- 7.1 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.
- 7.2 The Bolus Accessory Directions for Use labeling:
 - 7.2.1 Provides comprehensive directions for preparation and use for the Bolus Accessory.
 - 7.2.2 Describes the routes of administration as it relates to intended use.
 - 7.2.3 Contains warning information.
 - 7.2.4 Contains the prescription statement required under 801.109 (b)(1).

7.2.5 Includes the specifications of the Bolus Accessory . The specifications include the priming volume, residual volume, accuracy and operating conditions.

7.3 Identification labels and labeling

7.3.1 I-Flow has developed product identification labeling for the Bolus Accessory. Refer to Appendix B for examples.

7.4 Packaging labels

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

7.5 Appendix C contains predicate labeling for the I-Flow Paragon Bolus Accessory Set and the Baxter Patient Control Module.

8.0 STANDARDS

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

9.0 PACKAGING

9.1 The Bolus Accessory is packaged in a sealed Tyvek pouch, 12 pouches per case.

9.2 Packaging is suitable for radiation or ETO sterilization.

9.3 Package aging tests have been conducted on the Tyvek pouch. The results of bacterial dust challenge testing has determined that the Tyvek pouches used to package the disposable Bolus Accessory maintains sterility in excess of three years.

10.0 STERILIZATION

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

10.2 (b)(4)

(b)(4)

10.3

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

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

10.4.2 Either method may be used.

11.0 COMPARISON TO LEGALLY MARKETED DEVICES

See Table 1 that follows this section for more specific information.

11.1 Intended Use

11.1.1 The Bolus Accessory , the I-Flow Paragon Bolus Accessory Set, the Baxter Patient Control Module and the I-Flow Bolus Dispenser have the same intended use:

11.1.1.1 To deliver fixed boluses of medication upon demand by the patient or healthcare provider.

11.2 Comparison to the I-Flow Paragon Bolus Accessory Set (K984638).

11.2.1 The Bolus Accessory is identical to the Paragon Bolus Accessory with the exception of initial operating pressure.

11.2.1.1 The Bolus Accessory may connect to any positive pressure, continuous flow infusion pump with a source pressure of 8 to 17 psi and flow rates from 0.5 to 200 ml/hr. The Paragon Bolus Accessory may connect to any infusion pump with a 6 psi source pressure and flow rates from 0.5 to 10 ml/hr.

11.2.2 Both bolus accessories consist of plastic housing, medication reservoir, bolus button activator and wrist band.

11.2.3 Bolus Refill Cycle (i.e. Refill Time)

11.2.3.1 An infusion pump is the pressure source pushing fluid into the inlet port of the bolus accessories.

11.2.3.2 The time required to fill the bolus cavity is called the “refill time”.

11.2.3.3 Both the Bolus Accessory and the Paragon Bolus Accessory Set determine the refill time by the flow control orifice of the device they attach to. During the refill time, the patient cannot receive another full bolus of medication.

11.2.3.4 Refill times vary according to the flow rate of source infusion pump. See table below.

Nominal Flow Rate of Pressure Source (ml/hr)	Refill Time	
	(min)	(sec.)
(b)(4)	(b)(4)	
(b)(4)	(b)(4)	
		(b)(4)
		(b)(3)

11.2.3.5 As fluid flows into the bolus cavity, the diaphragm is continuously displaced until the cavity is full.

11.2.3.5.1 The bolus cavity is filled non-linearly, slower in the beginning and more rapidly towards the end of the refill cycle.

11.2.3.5.2 The bolus reservoir is 0.5 ml volume.

11.2.4 Bolus Activation

11.2.4.1 On the opposite side of the diaphragm is a bolus button. The button moves with the diaphragm as it is displaced.

11.2.4.2 At any time while the bolus cavity is filling, the button can be pressed by the user. Only when the bolus cavity is full will the patient receive the entire bolus.

11.2.4.3 When the button is pressed, the fluid in the bolus cavity is pushed out and forced through a check valve. At this point, the refill cycle begins.

11.3 Comparison to the Baxter Patient Control Module (K884505).

11.3.1 The Bolus Accessory is very similar to the Baxter Patient Control Module.

11.3.2 The Patient Control Module may connect to any Baxter Infusor to deliver fixed boluses of medication upon demand by the patient or healthcare provider.

11.3.3 The Patient Control Module consists of plastic housing, medication reservoir, bolus button activator and wrist bands.

11.3.4 Bolus Refill Cycle (i.e. Refill Time)

11.3.4.1 The Baxter Infusor is the pressure source pushing fluid into the inlet port of the Patient Control Module.

11.3.4.2 The time required to fill the bolus cavity is called the “refill time”.

11.3.4.3 Both the Bolus Accessory and the Patient Control Module determine the refill time by the flow control orifice of the device they attach to. During the refill time, the patient cannot receive another full bolus of medication.

11.3.4.4 Refill times vary according to the flow rate of the Baxter Infusor. See table below.

Flow Rate of Baxter Infusor (ml/hr)	Refill Time (min.)
0.5	60
2.0	15
5.0	6

11.3.4.4.1 The bolus cavity is filled linearly as opposed to non-linearly for the Bolus Accessory.

11.3.4.4.2 The bolus reservoir is the same as the Bolus Accessory (i.e. 0.5 ml volume).

11.3.5 Bolus Activation

11.3.5.1 For both the Bolus Accessory and the Baxter device, at any time while the bolus cavity is filling, the button can be pressed by the user. Only when the bolus cavity is full will the patient receive the entire bolus.

11.3.5.2 When the button is pressed, the fluid in the bolus cavity is pushed out and forced through a check valve. At this point, the refill cycle begins.

11.4 Comparison to the I-Flow Bolus Dispenser (K935811).

11.4.1 The I-Flow Bolus Dispenser is a stand alone device that does not need to connect to an infusion pump to deliver fixed boluses of medication.

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11.4.2 The Bolus Dispenser consists of a reusable plastic dispenser, disposable medication reservoir (plastic syringe or mini-bag) and disposable administration set.

11.5 Specifications

11.5.1 The Bolus Accessory, the I-Flow Paragon Bolus Accessory, the Baxter Patient Control Module and the I-Flow Bolus Dispenser have similar bolus volumes and refill times. See Table 1.

11.6 Materials

11.6.1 All fluid path materials of the Bolus Accessory are identical to the I-Flow Paragon Bolus Accessory and are in conformance with ISO 10993 Part 1.

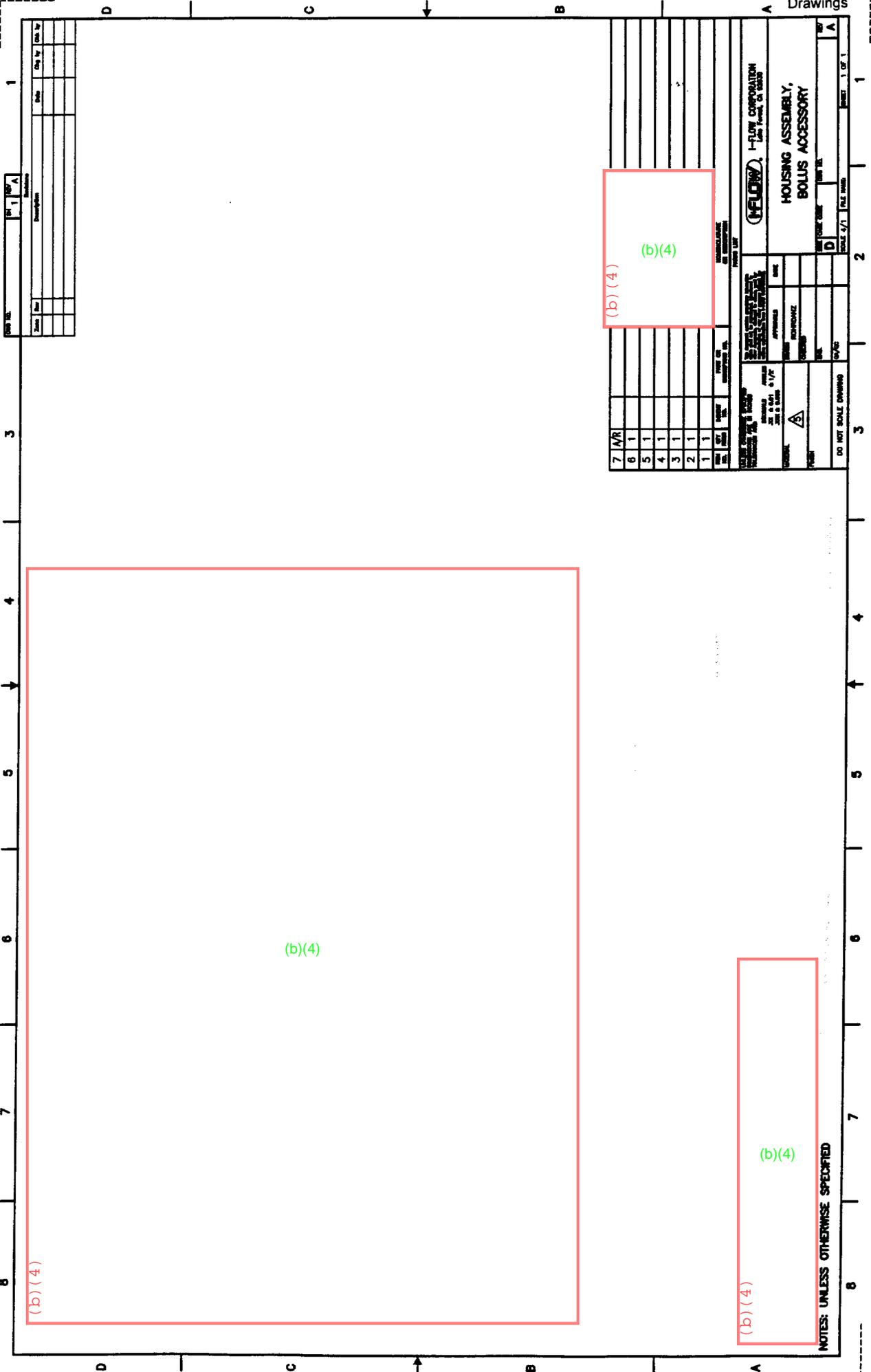
11.7 Based upon the data presented in this section 11.0 and Table 1, I-Flow Corporation has determined that the Bolus Accessory is substantially equivalent to the named predicate devices.

Table 1
Comparison to Legally Marketed Devices

Comparison Element	Bolus Accessory Set (subject device)	SE ¹ I-Flow Paragon Bolus Accessory Set (K984638)	SE ¹ Baxter Patient Control Module (K884505)	SE ¹ I-Flow Bolus Dispenser (K935811)
Intended Use	To deliver fixed boluses of medication upon demand by the patient or healthcare provider.	To deliver fixed boluses of medication upon demand by the patient or healthcare provider.	To deliver fixed boluses of medication upon demand by the patient or healthcare provider.	To deliver fixed boluses of medication upon demand by the patient or healthcare provider.
Route of Administration	Intravenous, epidural, intramuscular, subcutaneous, percutaneous and intra-operative	Intravenous, epidural, intramuscular and subcutaneous	Intravenous, epidural, intra-arterial and subcutaneous	Intravenous, epidural, intramuscular and subcutaneous
Contraindications	Not intended for delivery of blood, blood products, lipids or fat emulsions. Not for continuous medication delivery.	Not intended for delivery of blood, blood products, lipids or fat emulsions. Not for continuous medication delivery.	Not for continuous medication delivery.	Not intended for delivery of blood or blood products. Not for continuous medication delivery.
Reuse Capability	Disposable, Single Patient Only	Disposable, Single Patient Only	Disposable, Single Patient Only	Disposable, Single Patient Only
Description				
Bolus Volume	0.5 ml	0.5 ml	0.5 ml	0.25, 0.5 and 1.0 ml
Bolus Refill Times	3.6, 7.2, 18 and 72 min. 11, 22 and 43 sec.	3.6, 9, 18, 35 and 72 min.	variable (6 to 60 min.)	15, 30, 60 and 120 min.
Pump Type	Available for use with any positive pressure, continuous flow infusion pump with an internal operating pressure from 8 to 17 psi	Available for use with any 6 psi positive pressure, continuous flow infusion pump (e.g. Paragon pump)	Available for use with Baxter Infusor pump	Vacuum
Pump Volume	Varies	Varies	65 ml	30 ml
Power Requirements	None	None	None	None
Pressure Source	Various infusion pumps	Various 6 psi infusion pumps	Strain energy of elastomeric membranes	Vacuum
Safety / Alarm Functions	The non-linear refill add additional patient safety if the bolus button is pressed prior to the refill time.	The non-linear refill add additional patient safety if the bolus button is pressed prior to the refill time.		
Non-fluid Path Components	(b) (4)	(b) (4)		(b) (4)
Outer Bolus Housing				
Bolus Button				
Luer Caps				
Fluid Path Components	(b) (4)	(b) (4)		(b) (4)
Inner Housing				
Diaphragm (Bolus Reservoir)				
Check Valve				
Luer Adapters				
Tubing (make-up)				
Packaging (sterile pouch)	Tyvek Pouch	Tyvek Pouch		Tyvek Pouch
Sterilization	Gamma	Gamma or ETO		Gamma or ETO
Product Code	80 FPA	80 FPA		80 FPA

¹SE = Substantially Equivalent

Appendix A
Bolus Accessory Set Drawings



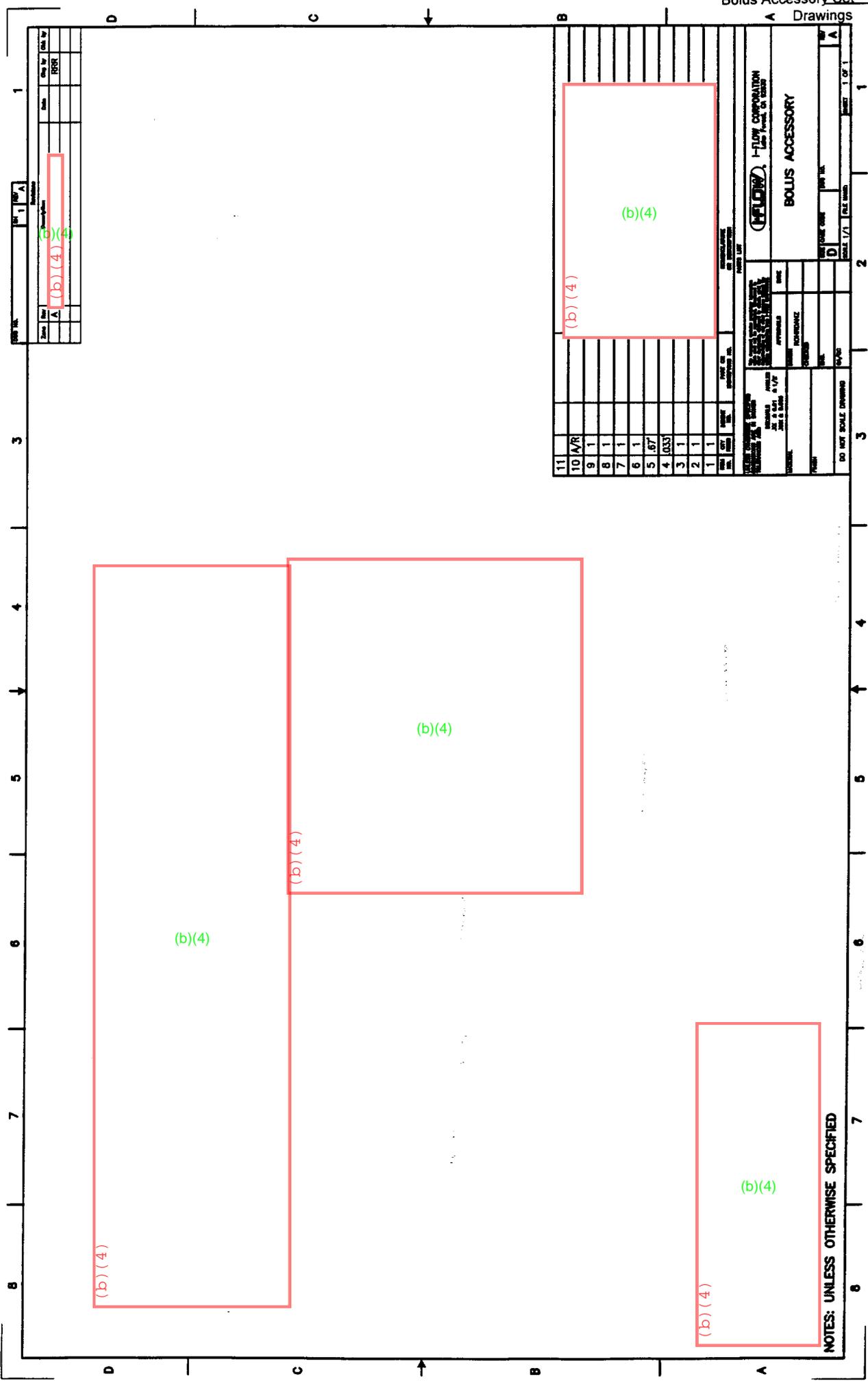
Zone	Size	Description	Date	Drawn by	Check by

REV	DATE	DESCRIPTION	BY	CHKD
7	1/1/17			
6	1/1/17			
5	1/1/17			
4	1/1/17			
3	1/1/17			
2	1/1/17			
1	1/1/17			

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 1-FLUX CORPORATION
 1-FLUX CORPORATION
 1-FLUX CORPORATION

**HOUSING ASSEMBLY,
 BOLUS ACCESSORY**

NOTES: UNLESS OTHERWISE SPECIFIED



Appendix B
Bolus Accessory Set Labeling

BOLUS

ACCESSORY SET

Directions for Use

NOMENCLATURE

1. Bolus Accessory Set ①
2. Female Luer ②
3. Wrist Strap ③
4. Bolus Button ④
5. Clamp ⑤
6. Distal End Cap ⑥

INDICATIONS FOR USE

The Bolus Accessory Set, in combination with a positive pressure, continuous flow infusion pump, is intended to allow fixed boluses of medication upon demand by the patient or healthcare provider. Refer to the infusion pump Directions for Use for additional instructions.

WARNING

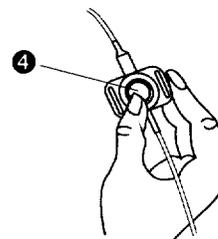
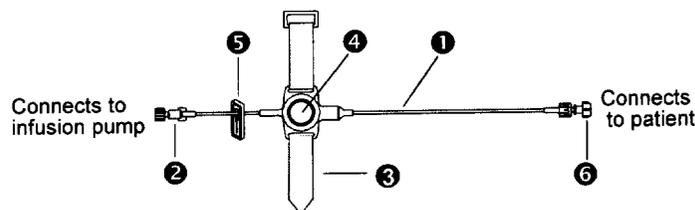
Attaching the Bolus Accessory Set to an infusion pump with an internal pressure source greater than 20 psi will cause a continuous flow condition at a reduced level of the source flow rate. For example, a 30 psi infusion pump will result in a continuous flow condition at approximately 1/3 of the source flow rate.

CAUTION

1. Do not use if package has been opened or is damaged or if either protector cap is not in place.
2. Epidural administration of analgesics is limited to use with indwelling catheters specifically indicated for either short-term or long-term analgesic drug delivery. Do not use Y adapter with epidural delivery.
3. If the device is to be used for epidural analgesic drug administration, it should be labeled to differentiate from other routes of administration. When using this device for epidural drug administration, make certain only drugs recommended for this route of administration are used.
4. The Bolus Accessory Set does not provide basal flow rate. It should be used in conjunction with another infusion line providing a continuous delivery when required to keep the IV line patent.
5. It is recommended that the Bolus Accessory Set be changed in accordance with established guidelines.
6. This product uses DEHP plasticized PVC. Certain solutions may be incompatible with the PVC material used in the Bolus Accessory Set. Consult the drug package insert and other available sources of information for a more thorough understanding of possible incompatibility problems.
7. The Bolus Accessory Set may deliver partial bolus volumes when used with high flow rate infusion pumps (i.e. 50 to 200 ml/hr) that don't contain a check valve. It is recommended that Model BA00005V be used with high flow rate infusion pumps.

CONTRAINDICATION

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



Single Patient Use.

The Bolus Accessory Set is sterile and non-pyrogenic. Do not resterilize.

THE BOLUS ACCESSORY SET

The Bolus Accessory Set is designed to allow the patient or healthcare provider to administer a 0.5 ml bolus on demand. The refill time for the bolus depends on the flow rate of the infusion pump to which the Bolus Accessory Set is attached. See the Refill Time Table for specific refill times.

Nominal Flow Rate of Pressure Source (ml/hr)	Refill Time	
	(min.)	(sec.)
Model BA00005 or BA00005V		
0.5	72	
2	18	
5	7.2	
10	3.6	
Model BA00005V		
50	0.72	43
100	0.36	22
200	0.18	11

The refill time can be approximated by dividing the bolus volume (0.5 ml) by the infusion pump flow rate (X ml/hr), multiplying by 60 to convert to minutes and multiplying by the refill factor (1.2).

$$\frac{0.5 \text{ ml}}{X \text{ ml/hr}} \times \frac{60 \text{ min.}}{1 \text{ hr}} \times 1.2 = \text{refill time (min.)}$$

NOTE

1. Actual refill times may vary from the specified range due to:
 - viscosity and/or drug concentration.
 - temperatures above or below the operating conditions.
 - the positioning of the attached infusion pump above or below the infusion site.
 - delivery pressure of the attached pump.
2. Designed for use with positive pressure continuous flow infusion pumps with delivery pressures in the range of 8-17 psi. The Bolus Accessory Set will not function properly with pressures outside this range.

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PRIMING THE BOLUS ACCESSORY SET

Method 1:

1. Prime the infusion pump first.
2. Attach the Bolus Accessory Set to the infusion pump. Slide clamp to open position.
3. Using aseptic technique, remove the distal end cap from the Bolus Accessory Set. Open the clamp on the infusion pump tubing. The medication will flow into the bolus chamber on the Bolus Accessory Set.
4. When the bolus button fills (button rises to top of housing), press the Bolus button to prime. Repeat until air is purged down stream from the bolus housing, which may take several pushes.
5. Close the infusion pump clamp and replace distal end cap.

Method 2:

1. Prime infusion pump first.
2. Using aseptic technique, remove distal end cap from the Bolus Accessory Set.
Do not discard cap.
3. Remove cap from female Luer and attach syringe with minimum 2 ml of solution or diluent.
4. Slide clamp to open position.
5. Inject solution until button rises to the top of the housing.
6. Slide clamp to closed position and depress bolus button to expel air from line.
7. Repeat Steps 4 - 6 until air is purged.
8. Slide clamp to open position and refill bolus reservoir from syringe.
9. Slide clamp to closed position, remove syringe and attach to the infusion pump. Slide clamp back to open position.
10. If diluent is used to prime the Bolus Accessory Set, be sure to expel the first bolus and allow to refill from infusion pump.
11. Replace distal end cap.

CHANGING INFUSION PUMP

1. If changing the infusion pump, first prime the new infusion pump.
2. Slide clamp to closed position on Bolus Accessory Set.
3. Detach old infusion pump and connect new infusion pump.
4. Slide clamp to open position on Bolus Accessory Set.

STARTING THE INFUSION

1. Attach the Bolus Accessory Set to the infusion site. Secure the bolus housing against the skin, using either the strap provided or tape.
2. Open the clamp on the infusion pump. A bolus can be delivered immediately.

BOLUS ACTIVATION

1. To receive a bolus of medication, press firmly down on the bolus button until it stops.
2. At any time during the infusion, the bolus button can be pushed to deliver a bolus of medication.
3. The next full bolus will be available after the refill time noted in the Refill Time Table.
4. Pressing the bolus button prior to the end of the refill time will result in a partial dose.

The Bolus Accessory Set Specifications

Bolus Volume: 0.5 ml

Refill Time: 0.18 min. - 72 min., depending on the nominal flow rate of the attached infusion pump.

Accuracy: Bolus Volume: $\pm 10\%$ at 95% confidence interval at the identified refill time.

Priming volume: Allow 1.5 ml for drug loss during priming.

Residual volume: Less than 0.75 ml (accessory only; does not include infusion pump).

CAUTION

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

For Customer Service
Call: 1.800.448.3569
949.206.2700
www.i-flowcorp.com



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

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LAKE FOREST, CA 92630
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CONTENU / CONTENIDO: 1



I-FLOW CORPORATION, LAKE FOREST, CA U.S.A.

REF BA00005

BOLUS ACCESSORY SET 0.5 ml Volume



STERILE



LOT

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

Manufactured by / Hersteller von /
Fabrique par / Fabricado por:
I-Flow Corporation
Lake Forest, CA 92630 U.S.A.

CE
0123

European Representative / Europäische Vertretung /
Représentant pour l'Europe / Representante Europeo:
MPS Medical Product Service GmbH
Borngasse 20, 35619 Braunfels, Germany

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CONTENU / CONTENIDO: 1



I-FLOW CORPORATION, LAKE FOREST, CA U.S.A.

REF BA00005V

BOLUS ACCESSORY SET 0.5 ml Volume (with Check Valve)



STERILE



LOT

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

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CONTENU / CONTENIDO: 12



I-FLOW CORPORATION, LAKE FOREST, CA U.S.A.

REF BA00005

BOLUS ACCESSORY SET 0.5 ml Volume



STERILE



LOT

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MPS Medical Product Service GmbH
Borngasse 20, 35619 Braunfels, Germany

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CONTENU / CONTENIDO: 12



I-FLOW CORPORATION, LAKE FOREST, CA U.S.A.

REF BA00005V

BOLUS ACCESSORY SET 0.5 ml Volume (with Check Valve)



STERILE



LOT

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

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Borngasse 20, 35619 Braunfels, Germany

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Appendix C
Bolus Accessory Set
Performance Data

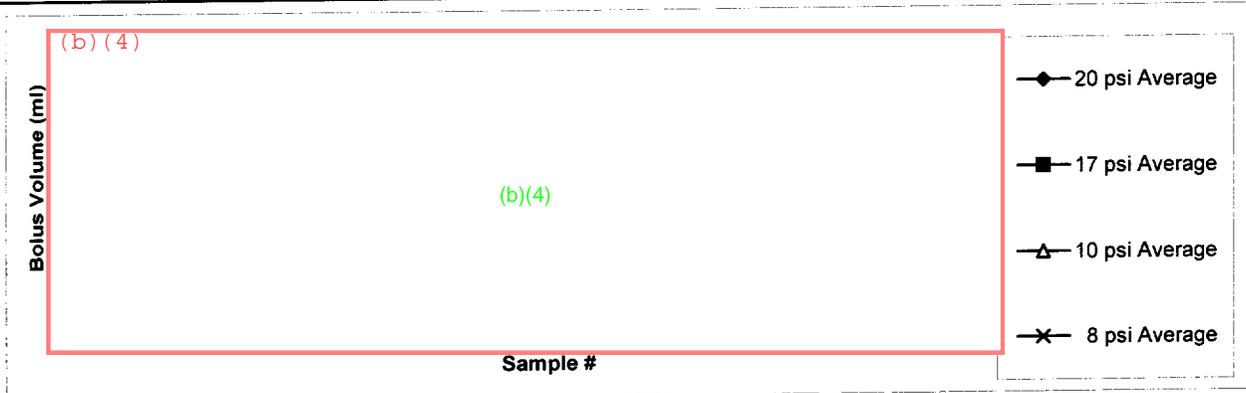
Chart #1
Bolus Accessory Volume (ml) Accuracy
 Source flow rate: 0.5 ml/hr
 Source pressure: 20, 17, 10 and 8 psi
 72 min lockout

Bolus Volume (ml) with 20 psi source		Average Bolus Volume (ml)
Bolus #	(b)(4)	(b)(4)
Min		0.52
Max		0.54
Average		0.54
N		10
Std. Dev.		0.01

Bolus Volume (ml) with 17 psi source		Average Bolus Volume (ml)
Bolus #	(b)(4)	(b)(4)
Min		0.49
Max		0.53
Average		0.52
N		10
Std. Dev.		0.01

Bolus Volume (ml) with 10 psi source		Average Bolus Volume (ml)
Bolus #	(b)(4)	(b)(4)
Min		0.47
Max		0.49
Average		0.48
N		10
Std. Dev.		0.01

Bolus Volume (ml) with 8 psi source		Average Bolus Volume (ml)
Bolus #	(b)(4)	(b)(4)
Min		0.47
Max		0.49
Average		0.48
N		10
Std. Dev.		0.00



Bolus Accessory Volume (ml) Accuracy

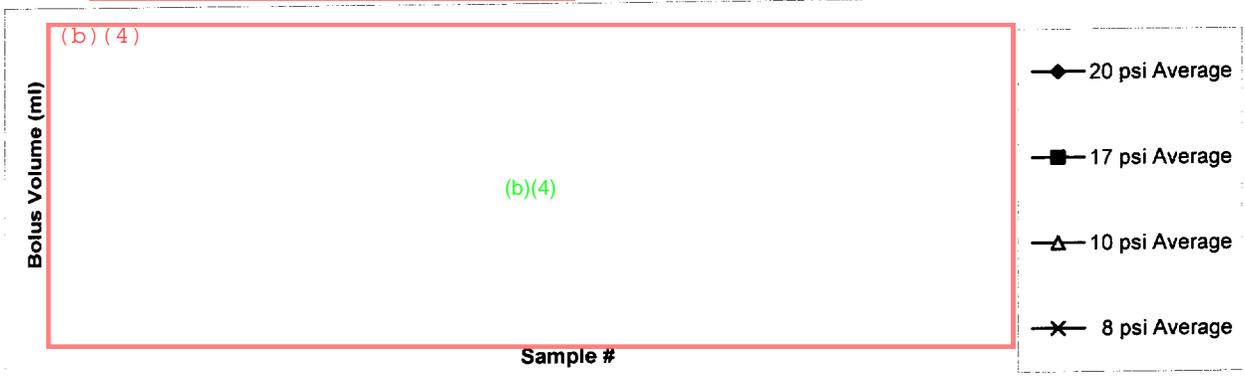
Source flow rate: 2 ml/hr

Source pressure: 20, 17, 10 and 8 psi

18 min lockout

Bolus Volume (ml) with 20 psi source		Average Bolus Volume (ml)	Bolus Volume (ml) with 17 psi source		Average Bolus Volume (ml)
Bolus #	(b)(4)	(b)(4)	Bolus #	(b)(4)	(b)(4)
Min		0.53	Min		0.51
Max		0.54	Max		0.53
Average		0.53	Average		0.52
N		10	N		10
Std. Dev.		0.00	Std. Dev.		0.01

Bolus Volume (ml) with 10 psi source		Average Bolus Volume (ml)	Bolus Volume (ml) with 8 psi source		Average Bolus Volume (ml)
Bolus #	(b)(4)	(b)(4)	Bolus #	(b)(4)	(b)(4)
Min		0.49	Min		0.48
Max		0.50	Max		0.49
Average		0.50	Average		0.49
N		10	N		10
Std. Dev.		0.00	Std. Dev.		0.00

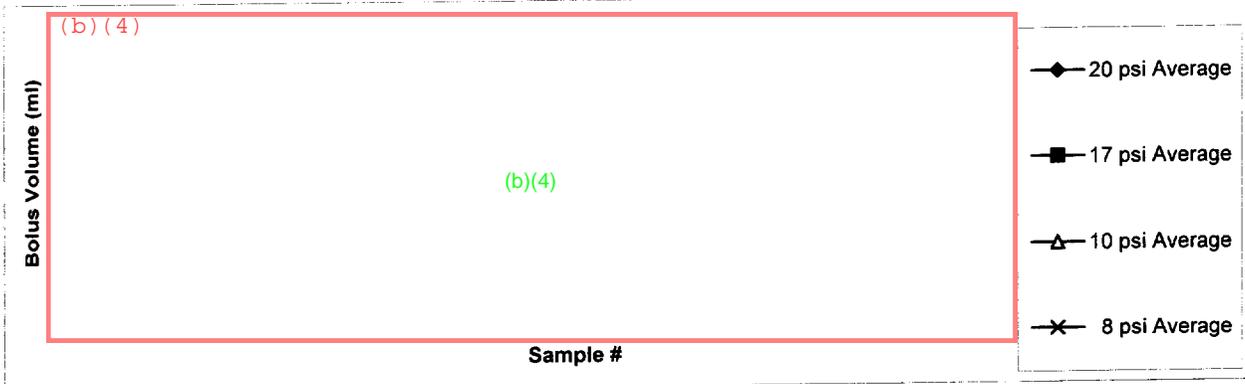
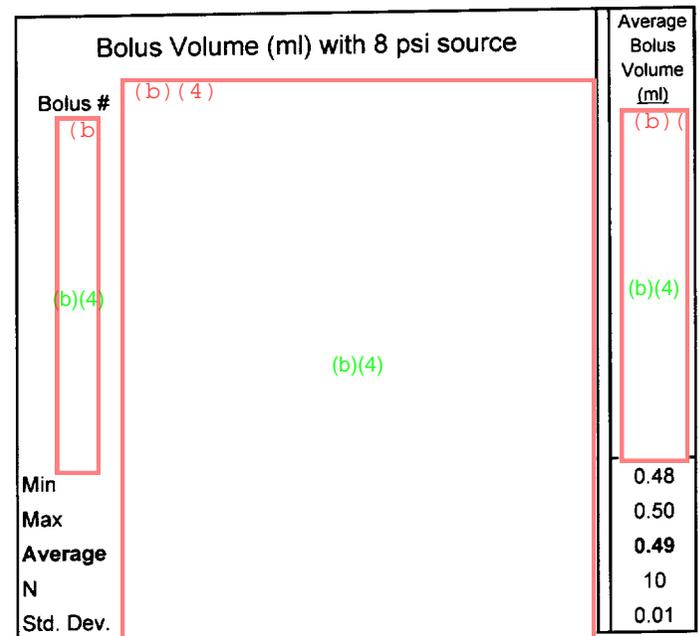
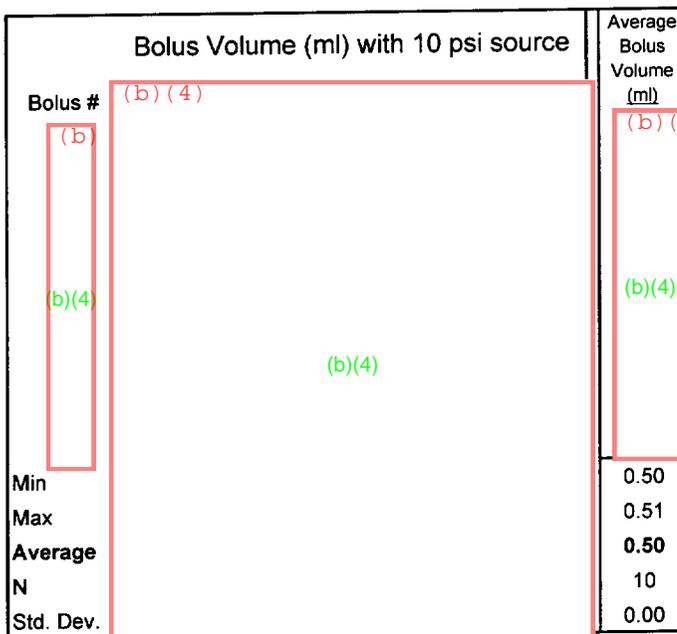
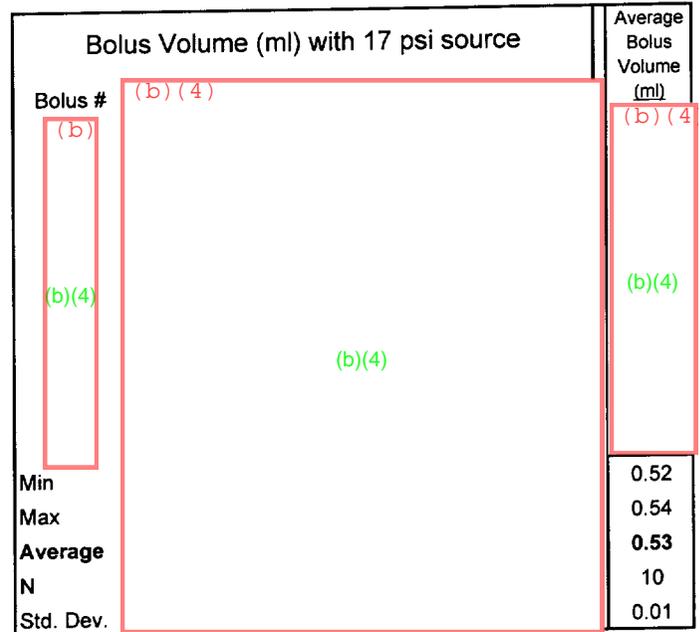
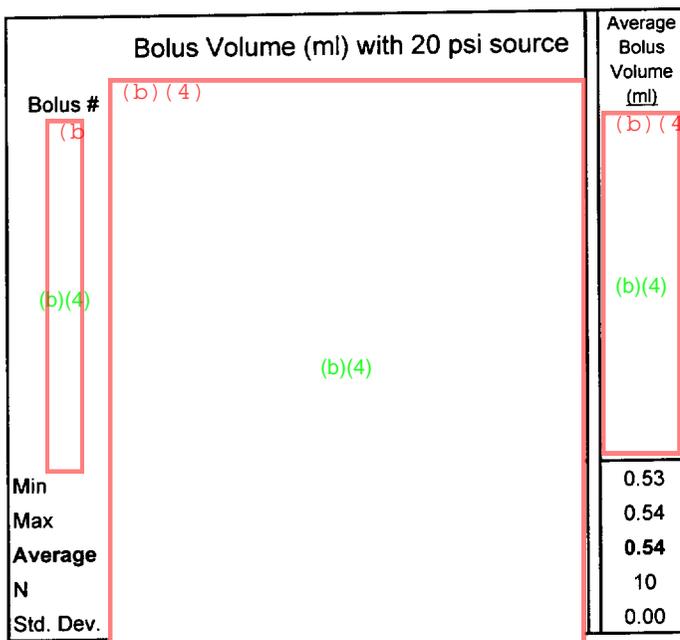


Bolus Accessory Volume (ml) Accuracy

Source flow rate: 5 ml/hr

Source pressure: 20, 17, 10 and 8 psi

7.2 min lockout



Bolus Accessory Volume (ml) Accuracy

Source flow rate: 10 ml/hr

Source pressure: 20, 17, 10 and 8 psi

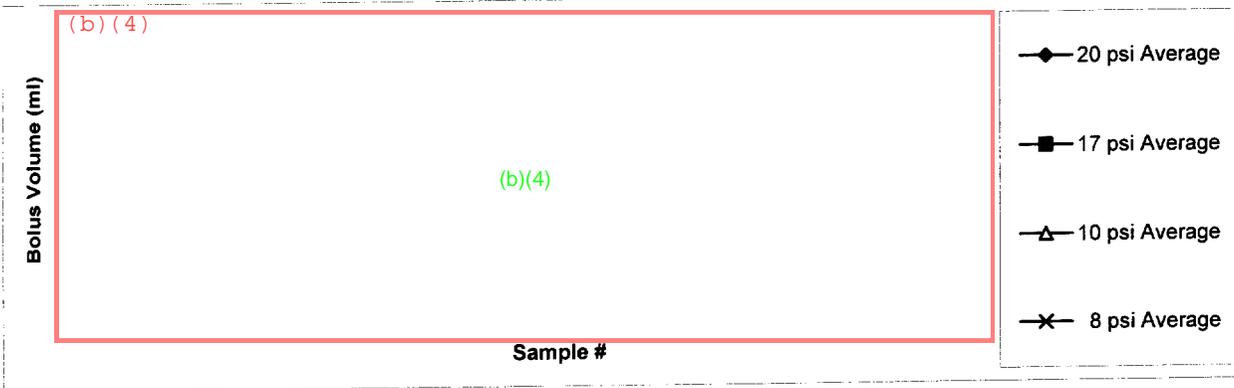
3.6 min lockout

Bolus Volume (ml) with 20 psi source		Average Bolus Volume (ml)
Bolus #	(b) (4)	(b) (4)
Min	(b)(4)	0.54
Max	(b)(4)	0.55
Average	(b)(4)	0.54
N	(b)(4)	10
Std. Dev.	(b)(4)	0.00

Bolus Volume (ml) with 17 psi source		Average Bolus Volume (ml)
Bolus #	(b) (4)	(b) (4)
Min	(b)(4)	0.52
Max	(b)(4)	0.54
Average	(b)(4)	0.53
N	(b)(4)	10
Std. Dev.	(b)(4)	0.00

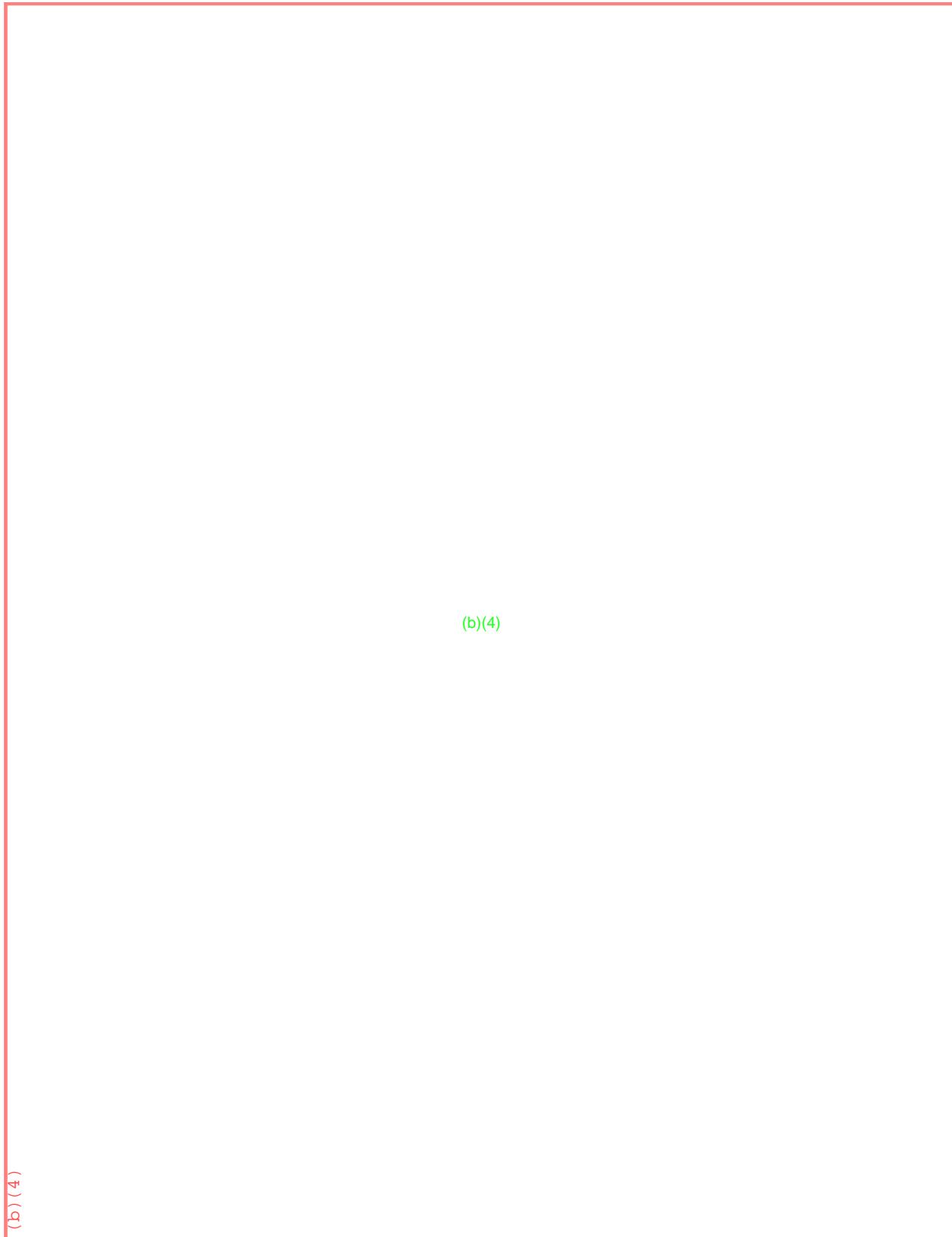
Bolus Volume (ml) with 10 psi source		Average Bolus Volume (ml)
Bolus #	(b) (4)	(b) (4)
Min	(b)(4)	0.50
Max	(b)(4)	0.51
Average	(b)(4)	0.50
N	(b)(4)	10
Std. Dev.	(b)(4)	0.00

Bolus Volume (ml) with 8 psi source		Average Bolus Volume (ml)
Bolus #	(b) (4)	(b) (4)
Min	(b)(4)	0.48
Max	(b)(4)	0.49
Average	(b)(4)	0.48
N	(b)(4)	10
Std. Dev.	(b)(4)	0.01



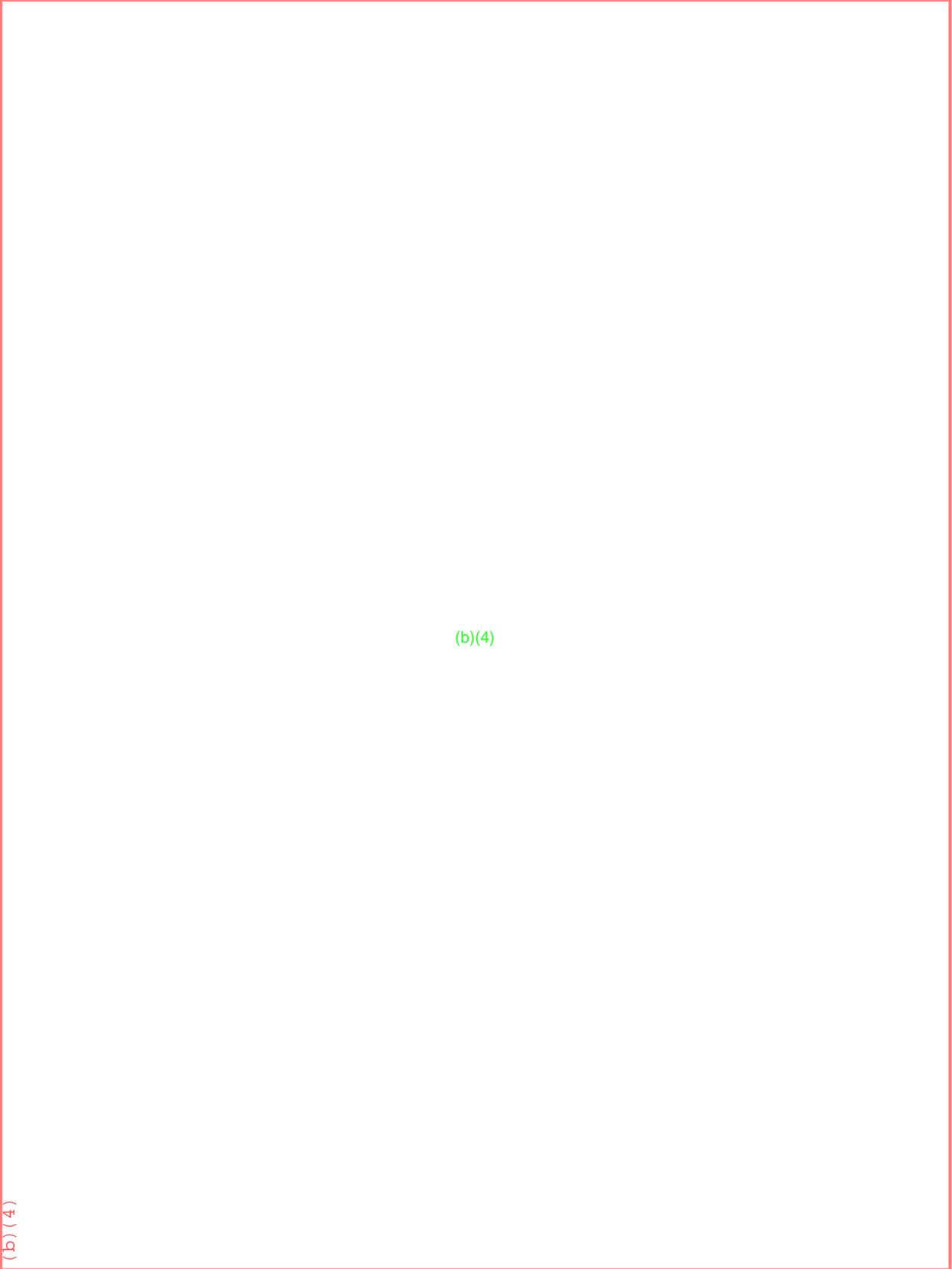
51

Chart #5
Bolus Accessory Volume (ml) Accuracy
Life Test
Bolus # 1 to 500



<u>Bolus # 1 to 500</u>	
Min	0.2
Max	0.6
N	500
Average	0.53
Std. Dev.	0.05

Chart #6
Bolus Accessory Volume (ml) Accuracy
Life Test
Bolus # 501 to 1000



(b)(4)

(b)(4)

<u>Bolus # 1 to 1000</u>	
Min	0.2
Max	0.6
N	1000
Average	0.53
Std. Dev.	0.05

Chart #7
Bolus Accessory Refill Time Accuracy
Life Test

Beginning of
1000 boluses
Time Vol.
After
1000 boluses
Time Vol.

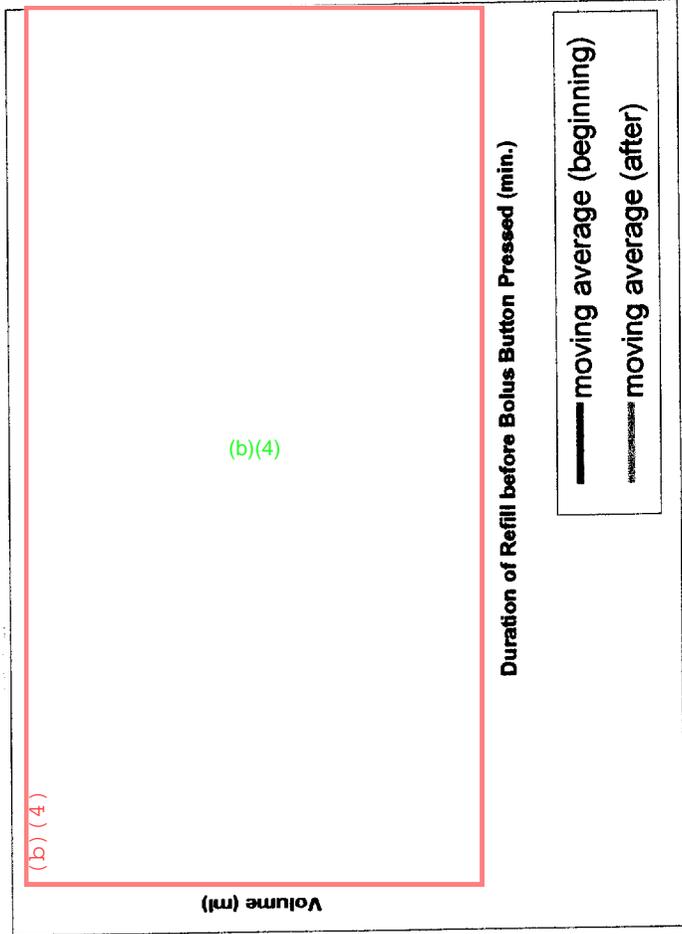
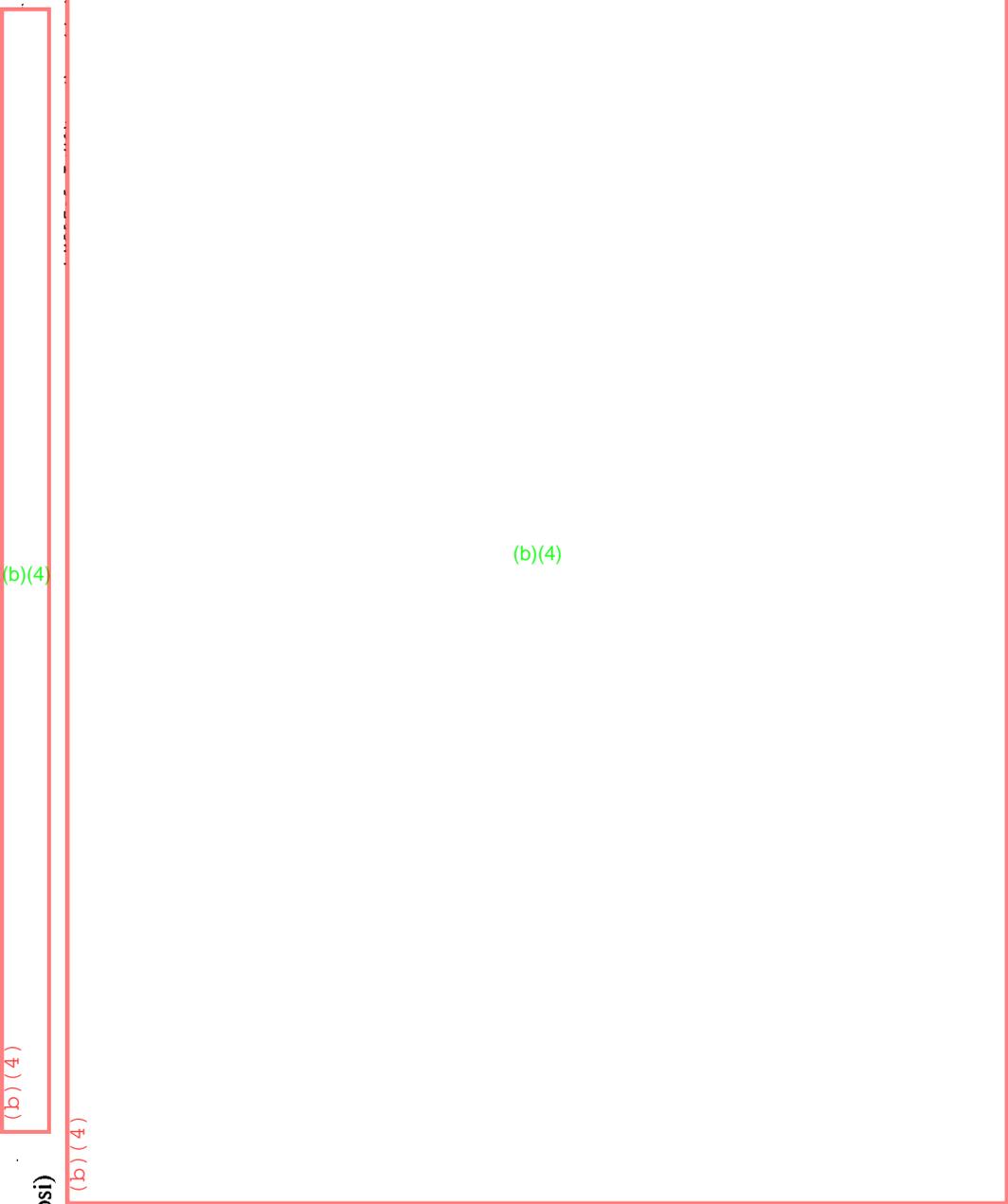


Chart #8a
Bolus Accessory Set
Pressure Profile
During Refill Cycle
3.6 min. lockout

ON IRVHD

Pressure (psi)

Time (min.)



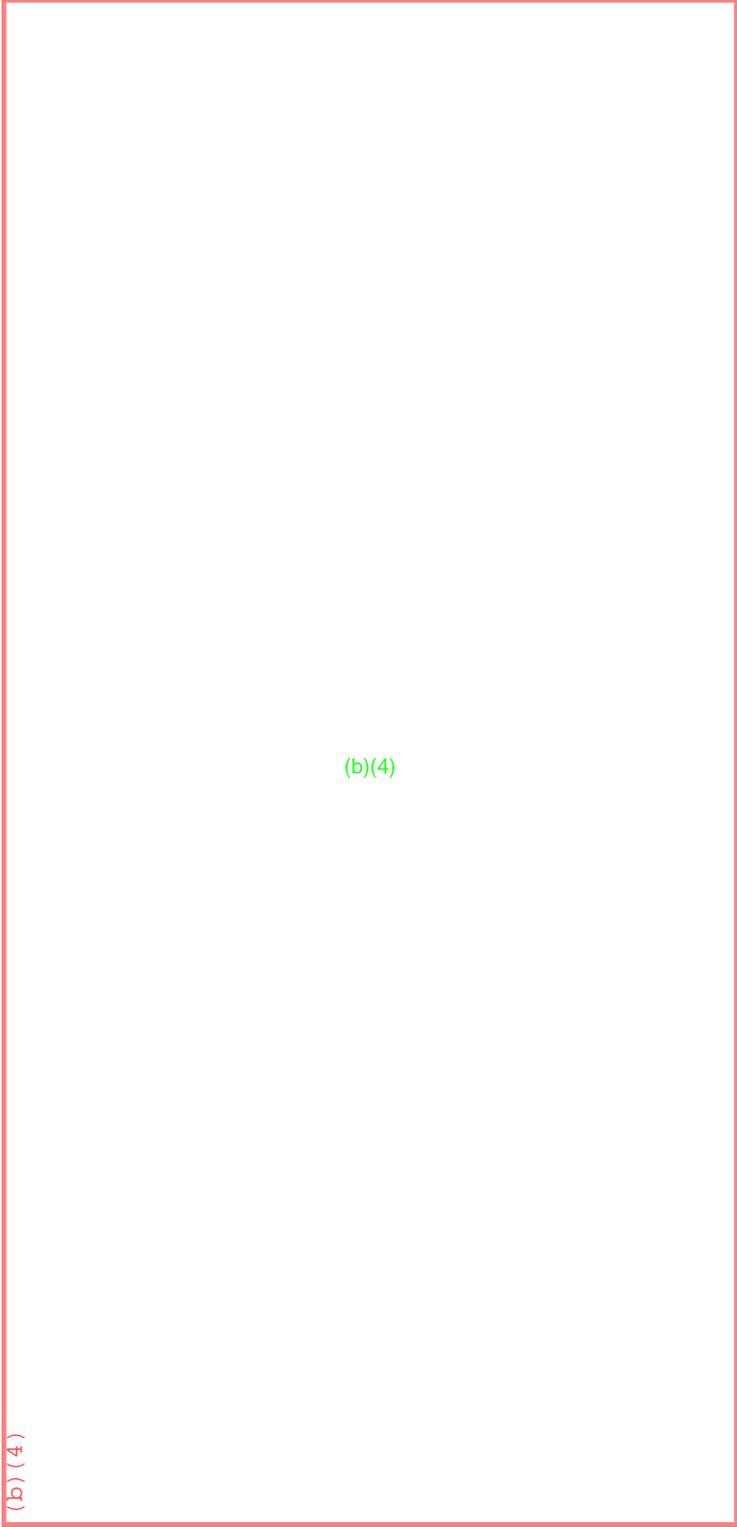
(b)(4)

(b)(4)

(b)(4)

Chart #8b
Baxter Patient Control Module
Pressure Profile
During Refill Cycle
6 min. lockout

(b)(4)



Pressure (psi)

Time (min.)

Appendix D
Predicate Labeling

PARAGON BOLUS ACCESSORY SET

Directions for Use

NOMENCLATURE

1. Bolus Accessory Set ①
2. Luer Lock ②
3. PARAGON Administration Set ③
4. Bolus Button ④

INTENDED USE

The Paragon Bolus Accessory Set, in combination with a Paragon Administration Set, is intended to allow patient controlled bolus delivery. The bolus component of the administration set enables fixed boluses to be delivered upon demand by the patient or healthcare provider. The routes of administration include intravenous, epidural, intramuscular and subcutaneous.

DO NOT USE IF PACKAGE HAS BEEN OPENED OR IS DAMAGED OR IF EITHER PROTECTOR CAP IS NOT IN PLACE. THE PARAGON BOLUS ACCESSORY SET IS STERILE AND NON-PYROGENIC.

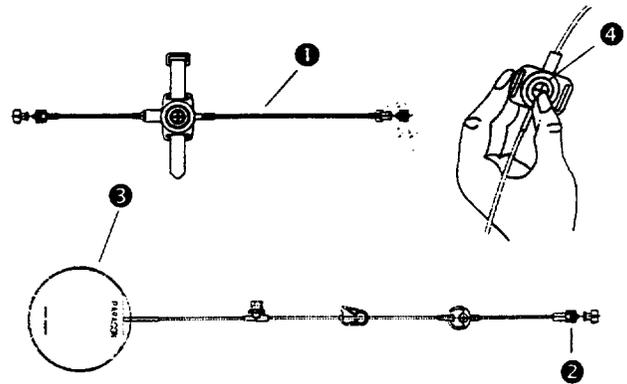
DO NOT RESTERILIZE. SINGLE PATIENT USE.

CAUTION

1. Not for blood, blood products, lipids or fat emulsions delivery. It is recommended that the Bolus Accessory Set be changed in accordance with established guidelines.
2. Epidural administration of analgesics is limited to use with indwelling catheters specifically indicated for either short-term or long-term analgesic drug delivery. Do not use Y adapter with epidural delivery.
3. If the device is to be used for epidural analgesic drug administration, it should be labeled to differentiate from other routes of administration. When using this device for epidural drug administration, make certain only drugs recommended for this route of administration are used.
4. The Bolus Accessory Set does not provide basal flow rate. It should be used in conjunction with another infusion line providing a continuous delivery in order to keep the IV line patent.
5. Refer to the Directions for Use for the Paragon Administration Set for additional instructions.

THE BOLUS ACCESSORY SET

The Paragon Bolus Accessory Set is designed to allow the patient or healthcare provider to administer a 0.5 ml bolus on demand. The refill time for the bolus depends on the Paragon Administration Set to which the Bolus Accessory Set is attached. See the Refill Time Table for specific refill times.



PRIMING THE ADMINISTRATION SET

1. Prime the administration set first.
2. Attach the Bolus Accessory Set to the administration set.
3. Using appropriate aseptic technique, remove the cap from the Luer lock at the end of the set. Open the clamp on the administration set tubing. The medication will flow into the bolus chamber on the Bolus Accessory Set.
4. When the bolus button fills (button rises to top of housing), press the Bolus button to prime. Repeat until air is purged down stream from the bolus housing, which may take several pushes.
5. Pinch the clamp closed and replace the cap.

STARTING THE INFUSION

1. Attach the Bolus Accessory Set to the infusion site. Secure the bolus housing against the skin, using either the strap provided or tape.
2. The Bolus button may be attached to the patient's wrist using the strap provided.
3. Opening the clamp on the administration set. A bolus can be delivered immediately.

BOLUS ACTIVATION

1. To receive a bolus of medication, press firmly down on the bolus button until it stops. ④
2. At any time during the infusion, the bolus button can be pushed to deliver a bolus of medication.
3. The next full bolus will be available after the refill time noted in the Refill Time Table.
4. Pressing the bolus button prior to the end of the refill time will result in a partial dose.

IMPORTANT

1. Only PARAGON administration sets distributed by I-Flow Corporation are authorized for use with this product. I-Flow Corporation accepts no responsibility for performance, or the liability for damages, caused by the misuse of this product when used with unauthorized administration sets.
2. This product uses DEHP plasticized PVC. Certain solutions may be incompatible with the PVC material used in the Bolus Accessory Set. Consult the drug package insert and other available sources of information for a more thorough understanding of possible incompatibility problems.

The PARAGON Bolus Accessory Set Specifications

Bolus Volume: 0.5 ml

Refill Time: 3.6 min. - 70 min., depending on the attached Paragon Administration Set.

Accuracy:

Bolus Volume: $\pm 10\%$ at 95% confidence interval at the identified lockout time.

Priming volume: Allow 1 ml for loss during priming.

Residual volume: Approximately 4 ml (including the Paragon Administration Set)

<u>Paragon Administration Set</u>	<u>Refill Time</u>
0.5 ml/hr	70 min.
1.0 ml/hr	35 min.
2.0 ml/hr	18 min.
4.0 ml/hr	9 min.
10.0 ml/hr	3.6 min.

NOTES

- Actual refill times may vary from the specified range due to:
 - viscosity and/or drug concentration.
 - temperatures above or below the operating conditions.
 - the positioning of the *PARAGON* Infuser above or below the infusion site.

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

For Customer Service
Call: 1.800.448.3569
949.206.2700



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

A PRODUCT OF

I-FLOW CORPORATION
LAKE FOREST, CA 92630
U.S.A.

1302268A
12/98

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A PRODUCT OF / EINE PRODUKT VON / UN PRODUIT DE / UN PRODUCTO DE CONTENTS / INHALT /
CONTENU / CONTENIDO: 1



I-FLOW CORPORATION, LAKE FOREST, CA U.S.A.

REF B000000

Paragon Bolus Accessory Set

0.5 ml bolus volume



STERILE



LOT

SEE DIRECTIONS FOR USE.

CAUTION: FEDERAL LAW (U.S.A.) RESTRICTS THIS DEVICE TO SALE BY OR ON THE ORDER OF A HEALTHCARE PROFESSIONAL.

Manufactured by / Hersteller von /
Fabrique par / Fabricado por:
I-Flow Corporation
Lake Forest, CA 92630 U.S.A.

CE
0123

European Representative / Europäische Vertretung /
Représentant pour l'Europe / Representante Europeo:
MPS Medical Product Service GmbH
Bomgasse 20, 35619 Braunfels, Germany

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CONTENTS / INHALT / CONTENU / CONTENIDO: 12

REF B000000

PART NO. 500XXXX

I-FLOW CORPORATION, LAKE FOREST, CA U.S.A.

Paragon Bolus Accessory Set

0.5 ml bolus volume



LOT

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

Manufactured by / Hersteller von /
Fabrique par / Fabricado por:
I-Flow Corporation
Lake Forest, CA 92630 U.S.A.



European Representative / Europäische Vertretung /
Représentant pour l'Europe / Representante Europeo:
MPS Medical Product Service GmbH
Borngasse 20, 35619 Braunfels, Germany

130XXXXA

2C1079

7-19-1-628



Infusor Patient Control Module

Description

The Patient Control Module is an accessory for Baxter's Infusors. When the medication demand button of the module is depressed, a small quantity of drug solution is delivered, nominally 0.5 mL. There is no infusion between depressions of the medication demand button.

Depression of the medication demand button empties the 0.5 mL reservoir of the Module. Upon release of the button, the reservoir again begins to fill with medication. The time to fill the Module's reservoir is determined by the Infusor selected. For example:

Infusor	Flow Rate	Approximate Module Fill Time
2C1070/2C1071	2 mL/hr	15 minutes
2C1073	5 mL/hr	6 minutes
2C1080	0.5 mL/hr	60 minutes
2C1954	0.5 mL/hr	60 minutes
2C1955	0.5 mL/hr	15 minutes

Note: All times reflect use of the Infusor as directed in the individual direction sheet.

Indications and Usage

The Patient Control Module is intended for use with patients in both the hospital and home environment. It is convenient for use by ambulatory or nonambulatory patients. **This accessory can only be used with Baxter's Infusors.**

Warnings

- To ensure proper performance the device should be used as directed.
- This accessory **must** be used with Baxter's Infusors to ensure safe operation.
- Do not use if white shipping insert is not affixed to the medication demand button when received.
- Remove white shipping insert prior to connection to patient. **Failure to remove shipping insert will cause continuous infusion.**

Not intended for use for continuous infusion.

Directions For Filling

Use aseptic technique throughout entire procedure

A. Standard Method

- Select the Infusor with the desired flow rate. Module filling time determines the maximum number of 0.5 mL doses available per hour.
- Prepare the Infusor per its enclosed direction sheet. The drug concentration should be set so that the unit delivers the maximum dose/hr prescribed by the physician at either the 6, 15, or 60 minute dose interval. The patient can then use the Module to titrate the drug within the prescribed limits.

- When the Infusor is ready for use, remove the tip protector and winged Luer cap from the Module. Do not remove white shipping insert at this time. Place the male Luer of Infusor into the female Luer of the Module. **Note: Avoid touch contamination of the Luer fittings.**
- The Module will be primed by the flow of the Infusor. Priming time will depend upon the flow rate of the Infusor selected.
- Observe the reservoir filling through the clear back plate. **When the liquid starts to flow from the male Luer, remove the white shipping insert. Failure to remove shipping insert will cause continuous infusion.** When the reservoir is filled, depress and release the medication demand button to complete the priming operation and expel any air in the reservoir.
- Replace the winged Luer cap onto the male Luer of the Module.
- Package the entire unit in the Infusor Dispenser Bag for transport to the patient.
- Store in a clean area, protected from sunlight. Refer to drug manufacturer's package insert for storage requirements.

B. Optional Method

- Proceed per standard method above, sections A.1 and A.2.
- When the Infusor is ready for use, remove the tip protector and winged Luer cap from the Module. **Remove the white shipping insert from the Patient Control Module. Failure to remove shipping insert will cause continuous infusion.** Using a syringe containing a minimum of 2 mL of solution or diluent, attach the syringe to the female Luer of the Module. While filling the Module reservoir, cycle the Module medication demand button as needed to eliminate air in the reservoir or tubing. Disconnect the syringe from the female Luer of the Module.
- Connect the male Luer of Infusor to the female Luer of the Module.
- Proceed per standard method above, sections A.6 through A.8. **Do not store above 38°C (100°F) or in direct sunlight.**

Baxter Healthcare Corporation
 Deerfield, IL 60015 USA

Printed in USA

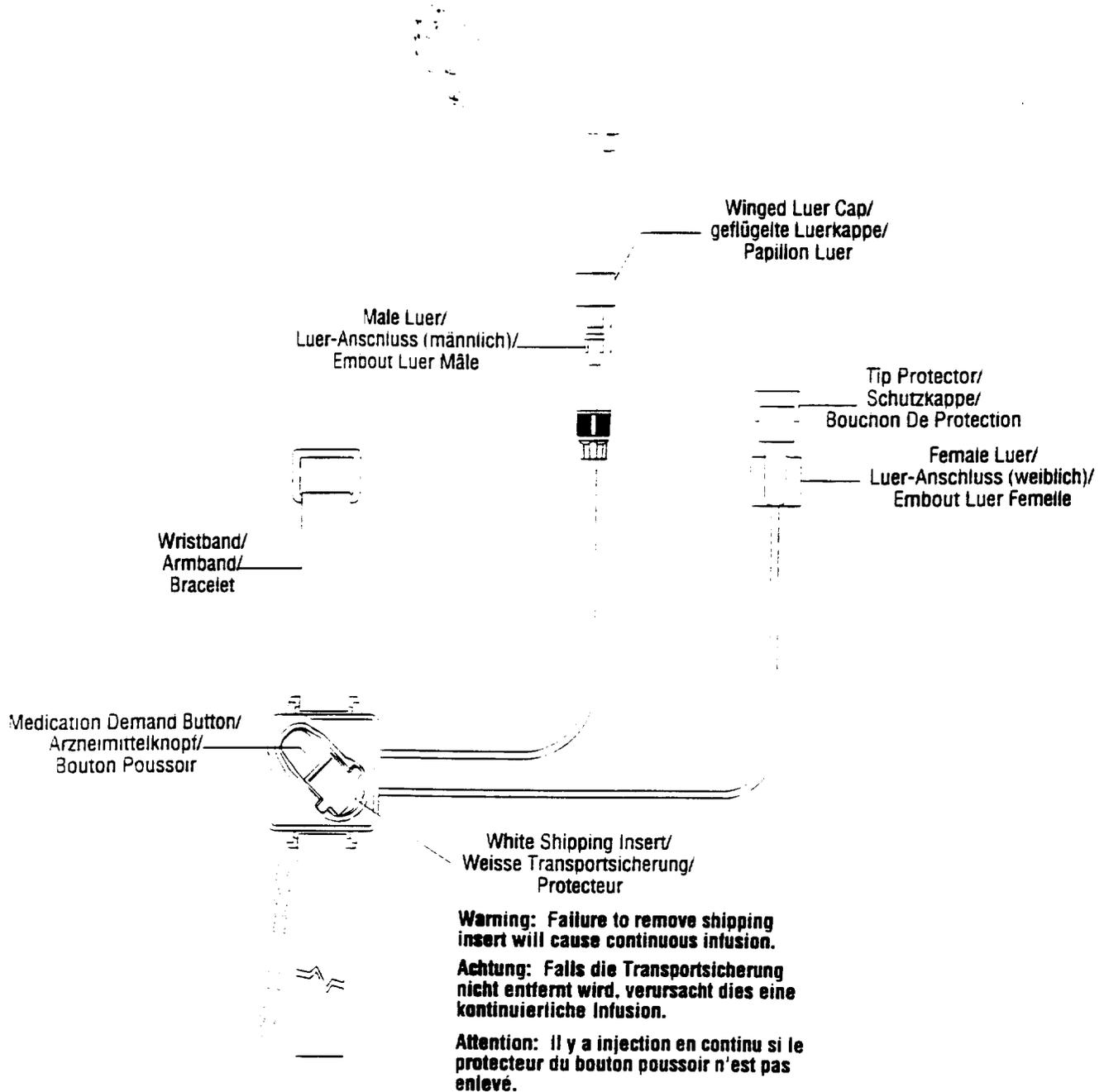
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7-19-1-628

Rev. March 1992

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Infusor Patient Control Module/Module De Contrôle Pour L'Infuseur/Watch



To Open Peel Down

2C1079

Baxter

Infusor Patient Control Module

Sterile, nonpyrogenic fluid path.

Do not use if tip protectors are not in place.

The Patient Control Module is intended for use in both the hospital and home environment by ambulatory or nonambulatory patients.

For use with Baxter's infusors only.

Not intended for use for continuous infusion.

Failure to remove shipping insert will cause continuous infusion.

See accompanying directions for use.

Caution: Federal (USA) law restricts this device to sale by or on order of a physician.

Do not store above 38°C (100°F) or in direct sunlight.

Baxter Healthcare Corporation

Deerfield, IL 60015 USA

Made in USA

Patent Pending

Module De Contrôle Pour L'Infuseur C1079

Circuit stérile et apyrogène.

Ne pas utiliser si les protecteurs des extrémités du circuit ne sont pas en place.

Vérifier l'intégrité du protecteur de stérilité avant usage.

N'ouvrir qu'au moment de l'emploi.

Mode d'emploi: Voir notice jointe; notamment, ne pas oublier de retirer le protecteur du bouton poussoir sous peine d'obtenir une injection en continu.

Stocker à une température inférieure à 38°C et à l'abri de la lumière.

Ne pas réutiliser—détruire après emploi.

Fabriqué par Baxter Healthcare Corporation, Deerfield, IL 60015, USA

Distribué par Baxter S.A. France—Avenue Louis Pasteur—
78311 Maurepas Cedex

Watch 2C1079

Für die bedarfsgesteuerte Therapie (on-demand)

Flussweg ist steril und pyrogenfrei.

Zum einmaligen Gebrauch.

Bei beschädigter Verpackung, gelockerten oder fehlenden Schutzkappen nicht verwenden.

Beiliegende Gebrauchsanweisung beachten.

Nicht über 38°C lagern. Vor direkter Sonneneinstrahlung schützen.

Baxter Deutschland GmbH

D-8044 Unterschleißheim

Sterilized by gamma irradiation/Stérilisé aux rayons gamma.

Lot/Numéro de lot/Ch.-B./

Manufacture Date/

Date of sterilization/Stérilisé

le/stérilisiert/

Expiration Date/Date de

péremption/Verwendbar bis:

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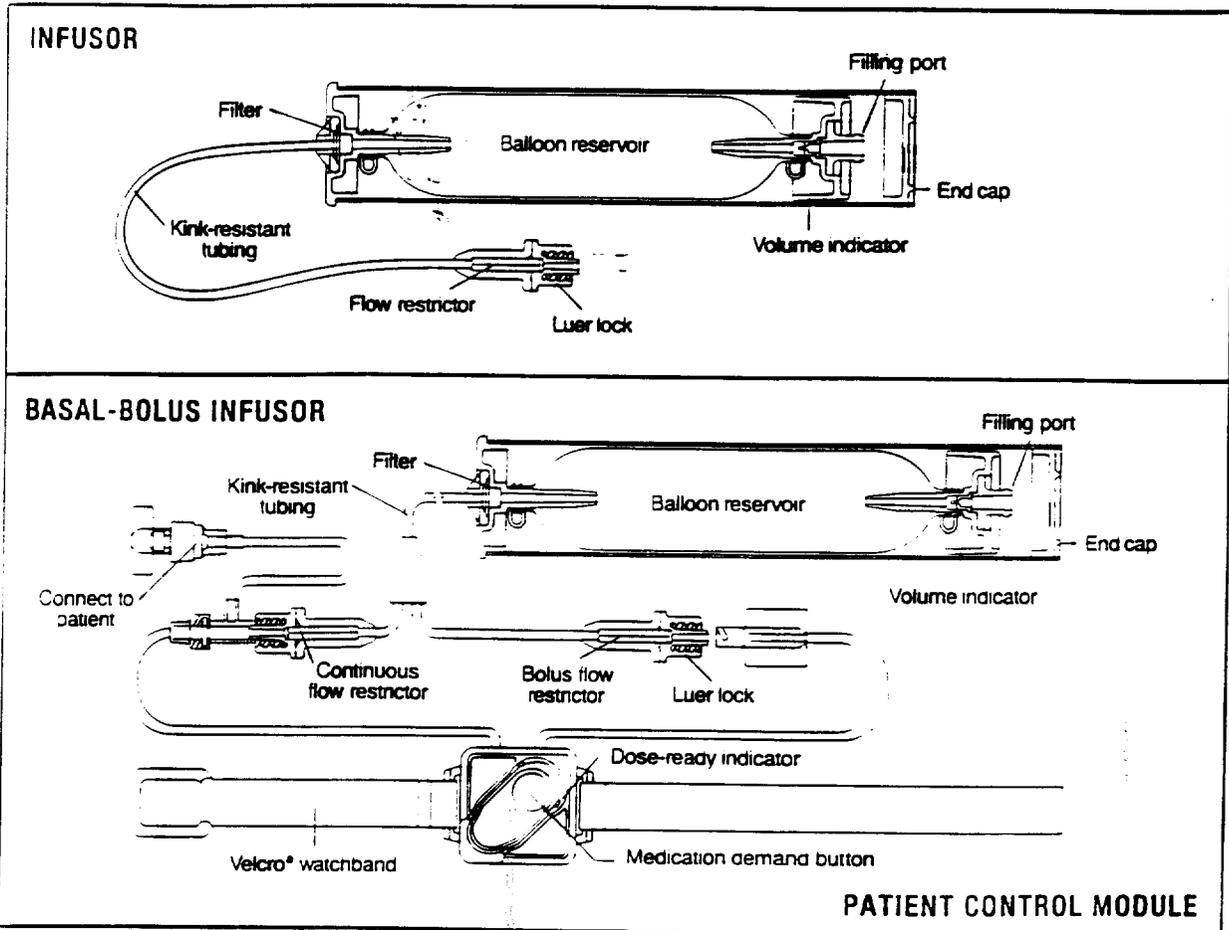
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04-11-93/
11-90/20-06-00

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PORTABLE INFUSION SYSTEMS WITH ELASTOMERIC TECHNOLOGY



Model	Number	Flow Rate	Lockout Time	Bolus Dose	Capacity	Units Per Case
Singleday Infusor	2C1071	2 mL/hr	15 min*	0.5 mL*	65 mL	6
12-hour Infusor	2C1073	5 mL/hr	6 min*	0.5 mL*	65 mL	6
Multiday Infusor	2C1080	0.5 mL/hr	-	-	65 mL	6
Basal-Bolus 15	2C1955	0.5 mL/hr	15 min	0.5 mL	65 mL	6
Patient Control Module	2C1079	-	-	0.5 mL	0.5 mL	12

*When used with Patient Control Module.

† Carlson RW, Siskic BI. Continuous infusion or bolus injection in cancer chemotherapy. *Ann Intern Med.* 1983;99:823-833.

Baxter

Baxter Healthcare Corporation, I.V. Systems Division, 1425 Lake Cook Road, Deerfield, IL 60015

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The Infusor System (Baxter)

DESCRIPTION

The Infusor System is a lightweight disposable device that uses a balloon reservoir to infuse medication. When filled, the Infusor System operates with a sustained internal pressure. Contents are delivered through a filter and a flow restrictor.

The Infusor System is designed to provide continuous flow of medication over the infusion period. Flow consistency is optimized when 5% Dextrose Injection (DSW) is used as the final diluent and the one-piece Luer body is in contact with the skin.

Indications and Usage

The Infusor System is indicated for patients requiring slow, continuous intravenous, intra-arterial, epidural or subcutaneous administration of medications. It is convenient for use by ambulatory patients.

It is the responsibility of the user to assure that the medication is prepared and administered in accordance with the drug manufacturer's package insert.

Epidural Administration

Epidural administration of analgesics is limited to use with indwelling catheters specifically indicated for either short-term or long-term analgesic epidural drug delivery.

To prevent infusion of drugs that are not indicated for epidural use, do not use administration sets that incorporate injection sites.

It is strongly recommended that Infusors used for epidural drug delivery be clearly differentiated from Infusors used for other routes of administration.

CONTRAINDICATIONS

Not designed for rapid infusion of medications.

WARNINGS

1. Epidural administration of drugs other than those indicated for epidural use could result in serious injury to the patient.
2. Discard Infusor after single use. The Infusor must not be refilled or resterilized.
3. Unfilled Infusors must be protected from direct sunlight and stored at temperatures less than 38°C (100°F).
4. Unfilled Infusors must be filled in accordance with the procedures described under DIRECTIONS FOR FILLING, in order to ensure proper performance.
5. Do not use unless solution is clear.
6. Do not fill with more than specified amount of solution. See directions accompanying Infusor.
7. Do not fill with more than maximum recommended fill volume.

MIXING AND USE INFORMATION

1. The Infusor System is a fixed rate device designed to flow at a nominal rate as specified in the labeling of each Infusor. The quantity of solution for the Infusor is prepared by diluting the desired dose of drug in the recommended diluent to a volume determined by the desired Infusor time.
2. Alteration of dosage is achieved by adjustments in concentration rather than flow rate.
3. Adhere to drug manufacturer's package insert if drug reconstitution is necessary.
4. The medication is prepared by diluting the desired dose of drug in a 60-mL syringe with Luer lip.
5. The Infusor System is designed to operate using 5% Dextrose Injection (DSW) as the final diluent to provide correct fluid viscosity. When using DSW, the Infusor will flow at the specified nominal rate. Although 0.9% Sodium Chloride Injection (NS) or Ringer's Injection may be used as an alternate diluent, these solutions will flow at approximately 10% above the nominal rate due to lower solution viscosity.

6. When empty, the Infusor will contain a 1 mL residual volume.

A. The fill volume for the Infusor is computed using the following equation:

1. Using DSW as the final diluent.

$$(\text{Infusion time} \times \text{nominal flow rate}) + 1 \text{ mL residual volume} = \text{fill volume.}$$
2. Using NS or Ringer's Injection as the final diluent.

$$(\text{Infusion time} \times 1.1 \times \text{nominal flow rate}) + 1 \text{ mL residual volume} = \text{fill volume.}$$

B. Compensate for the 1 mL residual volume using the following equation:

$$\text{Desired patient dose} \times \frac{\text{fill volume}}{\text{fill volume} - 1} = \text{total dose placed in Infusor}$$

For code 2C1082, substitute 2 mLs for residual volume.

U.S. Food and Drug Administration

DETAILED INFORMATION**Device Classification Name:** PUMP, INFUSION**Regulation Number:** 880.5725**510(k) Number:** K884505**Device Name:** BASAL/BOLUS INFUSORS**Applicant:** BAXTER HEALTHCARE CORP.

ROUTE 120 & WILSON ROAD

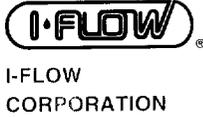
ROUND LAKE, IL 60073

Contact: PATRICIA S BARSANTI**Product Code:** FRN**Date Received:** 10/25/88**Decision Date:** 07/14/89**Decision:** Substantially Equivalent**Classification Advisory Committee:** General Hospital**Review Advisory Committee:** General Hospital**Statement/Summary/Purged Indicator:** Purged. no summary or statement[Return For Another Search](#)[CDRH Home Page](#)[FDA HOME PAGE](#)[COMMENTS](#)*(Database Updated April 6, 1998)*

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Appendix E
Summary of Safety and Effectiveness

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

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: $88 \pm 2^\circ\text{F}$ (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: $\pm 10\%$ 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.

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