I-FLOW
CORPORATION

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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
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1.0 GENERAL INFORMATION

1.1 Purpose of Submission

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

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

1.2 Statement of Equivalence

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

2.0 PHYSICAL SPECIFICATIONS AND DESCRIPTIONS

2.1 Description of the Bolus Accessory

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

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

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

2.2 Product Configuration

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

2.3 Components and Materials

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

2.4 Power Requirements

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

3.0 OPERATIONAL SPECIFICATIONS AND DESCRIPTIONS

3.1 Standard Operating Conditions:

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

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

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

3.3 **Safety/Alarm Functions**

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

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

4.0 BIOLOGICAL SPECIFICATIONS

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

5.0 CHEMICAL AND DRUG SPECIFICATIONS

5.1 Compatibility

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

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

6.0 INTENDED USE

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

6.2 The Bolus Accessory is not intended for continuous delivery.

6.3 The Bolus Accessory is single patient use only.

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

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

7.0 STANDARDS

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

8.0 PACKAGING

8.1 Packaging is suitable for radiation or ETO sterilization.

9.0 STERILIZATION

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

10.0 COMPARISON TO LEGALLY MARKETED DEVICES

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

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP 15 1999

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

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

Dear Mr. Fry:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Good Manufacturing Practice for Medical Devices: General (GMP) regulation (21 CFR Part 820) and that, through periodic GMP inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of

the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4690. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsmamain.html".

Sincerely yours,

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

Enclosure

I-FLOW
CORPORATION

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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 [redacted] and percutaneous.

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

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

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

(Optional Format 1-2-96)