2/9/99

I-FLOW CORPORATION

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K984638

SUMMARY OF SAFETY AND EFFECTIVENESS

December 30, 1998

Trade Name: Paragon 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 an accessory device for the Paragon Infusion System (K923875), originally identified as the SideKick 50 Plus and SideKick 100 Plus. This new accessory will be known as the Paragon Bolus Accessory Set, hereafter identified as the Bolus Accessory. No change will be made to the existing Paragon pump or administration sets.

1.1.2 Trade Name: Paragon Bolus Accessory Set

1.1.3 Common Name: Bolus Accessory Set

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 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

Wherever the Paragon pump and administration set are mentioned, they may be replaced by any constant 6 psi pressure system.

2.1.1 The Bolus Accessory may connect to any Paragon administration set 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.

3.0 OPERATIONAL SPECIFICATIONS AND DESCRIPTIONS

3.1 **Standard Operating Conditions:**

Bolus Volume:	0.5 ml
Refill Time:	variable
Priming/Residual Volume:	<=4 ml
Operating Temperature:	90 ± 2°F
Calibration Solution:	0.9% NaCl
Operating Pressure:	6.0 psi pressure source
Head Height:	0"
Accuracy:	bolus volume: ±10% at 95% confidence interval at the identified lockout 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 Funtions**

3.3.1 This device contains no alarms or indicators.

3.3.2 The non-linear refill adds additional patient safety if the bolus button is activated prior to the lockout 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 is intended to deliver fixed boluses of medication upon demand by the patient or healthcare provider.

6.2 The routes of administration intravenous, epidural, intramuscular and subcutaneous.

6.3 The Bolus Accessory is not intended for continuous delivery.

6.4 The Bolus Accessory is single patient use only.

6.5 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.

6.6 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 has the same intended use as the predicate Baxter Pain Control Module and the I-Flow Bolus Dispenser. The Bolus Accessory has similar bolus volumes and lockout times as its predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB - 9 1999

Robert J. Bard, Esq., R.A.C.
Vice President Regulatory and Legal Affairs
I-Flow Corporation
20202 Window Drive
Lake Forest, California 92630

Re: K984638
Trade Name: Paragon Bolus Accessory Set
Regulatory Class: II
Product Code: FPA
Dated: December 30, 1998
Received: December 31, 1998

Dear Mr. Bard:

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

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

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

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4692. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsmamain.html".

Sincerely yours,

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

Enclosure

510(k) Number (if known): K984638

Device Name: Paragon Bolus Accessory Set

Indications for Use:

1. The Paragon Bolus Accessory Set is intended to deliver fixed boluses of medication upon demand by the patient or healthcare provider. The routes of administration are intravenous, epidural, intramuscular and subcutaneous.

(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

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

510(k) Number K984638

(Optional Format 1-2-96)