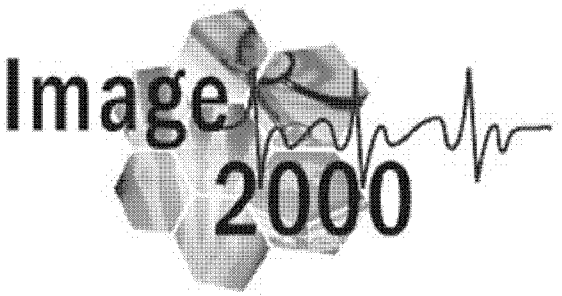

USER: MC GEEHAN, SANDRA K (skm)

FOLDER: K020251 - 85 pages (FOI:03008869)

COMPANY: I-FLOW CORP. (IFLOW)

PRODUCT: PUMP, INFUSION (FRN)

SUMMARY: Product: PARAGON INFUSION SYSTEM

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

DATE PRINTED: Wed Oct 18 09:21:31 2006

Note: FOI Working Copy

Table of Contents

FEB 1 5 2002

SPECIAL 510(K) - SUMMARY OF SAFETY AND EFFECTIVENESS

K020251

January 23, 2002

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

Contact: Shane Noehre
Manager of Regulatory Affairs
I-Flow Corporation

Trade Name: Paragon Infusion System

Common Name: Infusion Pump and Administration Set

Classification Name: Pump, Infusion

Existing Device: Paragon Infusion System (K923875, K984146, K984063, K984638)

Device Description: The Paragon Infusion System consists of a reusable mechanical infusion pump and various types of single use administration sets. This special 510(k) proposes a new line of administration sets that incorporates a variable flow rate mechanism.

Technology Comparison: The Paragon Infusion System with Variable Flow Rate utilizes the same technology for regulating flow rate (i.e. flow control tubing) and similar devices with variable flow rate components exist in the market (Novacon DIB-Infusor-RA – K960318 and Baxter Flow Regulator – K890489).

Conclusion: The Paragon Infusion System is substantially equivalent to the existing Paragon Infusion System and other variable flow rate devices currently being legally marketed.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB 1 5 2002

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

Re: K020251
Trade/Device Name: Paragon Infusion System
Regulation Number: 880.5440 and 880.5725
Regulation Name: Infusion Pump and Administration Set
Regulatory Class: II
Product Code: FPA and FRN
Dated: January 23, 2002
Received: January 24, 2002

Dear Mr. Noehre:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

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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

Ver/ 3 - 4/24/96

Applicant: I-Flow Corporation

510(k) Number (if known): _____

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1. The Paragon Infusion System is intended for continuous and/or intermittent infusion of medications for general infusion use, including antibiotic delivery, chemotherapy and pain management. Routes of administration include the following: intravenous, subcutaneous, intramuscular and epidural.
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(Division Sign-Off)
Division of Dental, Infection Control,
and General Hospital Devices
510(k) Number K020251

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Per 21 CFR 801.109)

(Optional Format 1-2-96)

FEB 1 5 2002

SPECIAL 510(K) - SUMMARY OF SAFETY AND EFFECTIVENESS

K020251

January 23, 2002

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

Contact: Shane Noehre
Manager of Regulatory Affairs
I-Flow Corporation

Trade Name: Paragon Infusion System

Common Name: Infusion Pump and Administration Set

Classification Name: Pump, Infusion

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Conclusion: The Paragon Infusion System is substantially equivalent to the existing Paragon Infusion System and other variable flow rate devices currently being legally marketed.

1.0 GENERAL INFORMATION

1.1 Purpose of Submission

1.1.1 This submission is intended to notify the Federal Food and Drug Administration that I-Flow intends to make a device modification to our own legally marketed device. The change affects the Paragon administration sets of the *Paragon Infusion System*. A new optional component for the Paragon administration sets will incorporate a variable flow rate component.

1.1.2 The existing (unmodified) Paragon administration sets have been cleared under the following 510(K)s:

- K923875 – the initial Paragon premarket notification (originally identified as the SideKick Plus).
- K984146 – added intraoperative and percutaneous routes of administration, added the Y-adapter models, added convenience kit models.
- K984063 – added the basal with bolus models.
- K984638 – added the bolus only accessory model.

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

1.1.4 Common Name: Infusion Pump and Administration Set

1.1.5 Classification Name: Pump, Infusion

1.1.6 Product Code: FRN

1.1.7 Device Classification: Class II, 880.5725

1.1.8 Medical Specialty: General Hospital

2.0 PHYSICAL SPECIFICATIONS AND DESCRIPTONS

2.1 Description of Device

The Paragon Infusion System consists of two main components, the Paragon pump and administration set. This premarket notification proposes a new line of administration sets, i.e. the Variable Flow Rate Sets. No change will be made to the Paragon infusion pump.

2.2 The Paragon Pump

2.2.1 The Paragon pump consists o
pump has internal threads which mate to the external threads of the
l

2.2.2

2.2.3 The allow for positioning of the administration set.

2.2.4 When he pump are fully threaded together, bag and acts as the pressurizing elemer

2.3 The Paragon Administration Sets

See Appendix B for drawings.

2.3.1 The Paragon administration sets consist of a drug bag attached to the administration line. The drug bag and administration line may be permanently bonded together or sold separately. The drug bag is filled with medication via a fill port. All Paragon administration sets are needleless and utilize standard ANSI compliant luer lock connectors. The sets may be used with an uch as the Paragon pump or another infusion pump. The administration line may incorporate any of the following optional components:

2.3.1.1

Note: All these features with the exception of the variable flow component have been cleared in previous 510(k)s.

2.3.2 The Variable Flow Component:

2.3.2.1 This component has seven flow rates which can be selected The dial is labeled with each flow rate and a "key" is used to rotate the dial from position to position. As a flow rate is dialed in, a tactile click can be felt. After the healthcare provider has selected the flow rate, the key may be removed and the dial cover is closed and tied off to prevent inadvertent changes to the flow rate.

See section **3.0** for model configurations.

2.3.2.2 The device contains As the dial is turned, which varies the flow rate. For example, model 1 contains

the dial is moved from one labeled flow rate to the next the following occurs:

Dial Position	Microbore Tubing			Net Flow Rate (ml/hr)
	0.5 ml/hr	1.0 ml/hr	2.0 ml/hr	

Thus the OFF position starts with
When
the rer

is pinched off and the
When diale

remains
rate. This continues as the dial is
position.

2.4 **Flow Control**

2.4.1 The fundamental scientific technology for controlling the flow rate remains the same as the existing (unmodified) Paragon administration sets.

2.4.2 Each administration set consists of a

2.4.3 The flow When
the bag is pressured by the Paragon infusion pump, the flow rates are approximated by

2.4.4 Where Q is the flow rate, p is the pressure drop D is the inside diameter of is the dynamic viscosity of the fluid and L is the length of the The equation provides an approximation of the actual delivery time.

3.0 NEW MODELS

3.1 (optional) Variable Flow Rate Component

This optional component replaces combination of flow rates to be selected by the healthcare provider. The following models will be available:

3.1.1 Model 1: combination

3.1.2

3.1.3

4.0 COMPONENTS AND MATERIALS

Note: No changes in materials will be made to the Paragon infusion pump. All fluid path materials in the Paragon administration sets are in compliance with ISO 10993 prior to market distribution.

The Paragon infusion pump is re-usable. The Paragon administration sets are disposable and single use only.

5.0 OPERATIONAL SPECIFICATIONS AND DESCRIPTIONS

5.1 Standard Operating Conditions:

Priming/Residual Volume:

Operating Temperature: ıriable Flow Rate set

Test Solution: aline

Operating Pressure: e source

Head Height:

Accuracy: onfidence interval

5.2 **Power Requirements:** The Paragon Infusion System is a pump for power. No additional external power source is required to operate.

5.3 Safety/Alarm Functions

5.3.1 The Paragon Infusion System such is not subject to fluid runaway conditions similar to that of some electronic pumps.

5.3.2 If for any reason the patient needs to stop his or her infusions, each administration set is supplied with a pinch clamp to stop the infusion.

5.3.3 This device contains no alarms or indicators for flow other than visual except

5.3.4 This device contains in line; however, each set may include

6.0 BIOCOMPATIBILITY SPECIFICATIONS

6.1 Biocompatibility testing is in conformance with ISO 10993 Part 1 for all fluid path components based on intended application of the device prior to market distribution.

7.0 CHEMICAL AND DRUG SPECIFICATIONS

7.1 Compatibility

7.1.1 There are no specific drugs referenced in the labeling for the Paragon Infusion System.

7.1.2 The Paragon Infusion System is intended for general purpose drugs and pain medication.

7.2 Drug Stability

7.2.1 There are no specific drugs referenced in the labeling for the Paragon Infusion System.

8.0 INDICATIONS FOR USE

8.1 There is no change to indications for use.

8.2 The Paragon Infusion System is intended for continuous and/or intermittent infusion of medications for general infusion use, including antibiotic delivery, chemotherapy and pain management. Routes of administration include the following: intravenous, subcutaneous, intramuscular and epidural.

8.3 The Paragon Infusion System is also intended for continuous and/or intermittent delivery of medication (such as local anesthetics or narcotics) to surgical wound sites for postoperative regional anesthesia and pain management. Routes of administration may be intraoperative or percutaneous.

8.4 The Paragon infusion pump may be used multiple times. The Paragon administration sets are single use only.

8.5 The Paragon Infusion System is suitable for use as an ambulatory device and is intended for use in the hospital, home environment or alternative care sites.

9.0 LABELS AND LABELING

9.1 The only change to the labeling will be for clarification of use of the variable flow rate component.

9.2 I-Flow Corporation believes the proposed labels and labeling, where appropriate, meets the requirements of 21 CFR Part 801 as it relates to a determination of intended use and adequate directions for use.

9.3 The Paragon Infusion System Directions for Use labeling:

9.3.1 Provides comprehensive directions for preparation and use for the Paragon Infusion System.

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

9.3.3 Contains warning information.

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

9.3.5 Includes the specifications of the Paragon Infusion System. The specifications include the priming volume, residual volume, accuracy and operating conditions.

9.4 Identification labels and labeling

9.4.1 I-Flow has developed product identification labeling for the Paragon Infusion System. Refer to Appendix C for examples.

9.5 Packaging labels

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

10.0 STANDARDS

10.1 There are currently no standards established for mechanical infusion devices.

11.0 PACKAGING

11.1 There is no change in the packaging. Packaging is in conformance with the standard EN 868-1 (Packaging Materials and Systems for Medical Devices which are to be Sterilized).

11.2 The Paragon Infusion System is packaged in a

11.3 Packaging is suitable for gamma radiation or

11.4 Package aging tests have been conducted on the sults of determined th used to package the disposable Paragon administration sets maintain sterility up to five years.

12.0 STERILIZATION

12.1 There is no change in the sterilization methods.

12.2 The methods of sterilization are

12.3 Sterilization validation methodol

12.3.1 The

12.4 Sterilization validation methodology is by

12.4.1

12.4.2

12.5 The sterile product under review here will have a sterilization assurance level (SAL) of 10^{-6}. Sterility testing is by Under product, no sterility test is required.

12.6 The Paragon Infusion System is labeled pyrogen free and is tested for pyrogens using either the

12.6.1 I-Flow products have been

12.6.2 Either method may be used as necessary.

13.0 COMPARISON TO THE EXISTING (UNMODIFIED) PARAGON ADMINISTRATION SETS

13.1 Intended Use

13.1.1 No change in intended use.

13.2 Fundamental Scientific Technology

13.2.1 No change in technology.

13.2.2 The Paragon Infusion System is identical to the existing Paragon Infusion System with the exception of the variable flow component. The variable flow component utilizes the same technology for controlling the flow rate as other Paragon administration sets (

13.3 Operational Specifications

13.3.1 No change in specification otl

13.3.2 The operational specifications for the variable flow rate sets are the same as the existing (unmodified) Paragon Infusion System except for the le flow rate sets are calibrated at unmodified) low flow rate Paragon sets are

13.4 No change in sterilization or packaging.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB 1 5 2002

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

Re: K020251
Trade/Device Name: Paragon Infusion System
Regulation Number: 880.5440 and 880.5725
Regulation Name: Infusion Pump and Administration Set
Regulatory Class: II
Product Code: FPA and FRN
Dated: January 23, 2002
Received: January 24, 2002

Dear Mr. Noehre:

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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

Ver/ 3 - 4/24/96

Applicant: I-Flow Corporation

510(k) Number (if known): _____

Device Name: Paragon Infusion System

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(Division Sign-Off)
Division of Dental, Infection Control,
and General Hospital Devices
510(k) Number K020251

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Per 21 CFR 801.109)

(Optional Format 1-2-96)

Food and Drug Administration
Center for Devices and
Radiological Health
2098 Gaither Road
Rockville, MD 20850

Medical Device Tracking Order
-Notice of Rescission-

May 1, 2003

RE: Electromechanical Infusion Pumps

Dear Medical Device Manufacturer:

The medical device tracking order that this office issued to you, is hereby rescinded, effective immediately.

Tracking orders were issued due to a new requirement of section 519(e) of the Federal Food, Drug and Cosmetic Act (the Act), as amended by the Food and Drug Administration Modernization Act of 1997 (FDAMA). Under section 519(e), as revised by FDAMA, the Food and Drug Administration (FDA) has discretion in the issuance of tracking orders to manufacturers of devices that meet the statutory criteria. Until the public had an opportunity to comment on the factors that should be examined in exercising that discretion and the agency's proposed implementation of tracking, as amended by FDAMA, FDA issued orders to manufacturers of all devices that it believed met the statutory criteria.

The agency's proposed implementation of tracking was explained in the "Guidance on Medical Device Tracking," which was published on March 4, 1998. The guidance explained the agency's statutory basis to decide whether a device needs to be tracked. The guidance also proposed a list of devices it believed should be tracked. The agency asked for public comment on its proposed list of tracked devices and on additional nonbinding factors that FDA should consider in exercising its discretion to require tracking for devices that meet the statutory criteria.

Based on the comments received and a review of the agency's premarket and postmarket information, FDA believes the following additional factors should be considered to determine whether a tracking order for a device meeting the statutory criteria should be issued:

(A) likelihood of sudden, catastrophic failure
(B) likelihood of significant adverse clinical outcome; and
(C) need for prompt professional intervention.

The agency may add or remove devices from the list of tracked devices as a result of its review of premarket applications, recall data, medical device reporting, inspections, petitions, postmarket surveillance or other information coming to its attention.

After considering these factors, FDA no longer believes that your device needs to be tracked to protect the public health and is rescinding its tracking order. The rescission of the tracking order issued to you does not change your obligations concerning other existing FDA regulations affecting your device. FDA may publish in the **Federal Register** further announcements concerning your device or the medical device tracking requirements under 21 CFR 821. Please contact Mr. Chet Reynolds in the Office of Compliance at (301) 594-4618 if you need specific guidance. Other general information on your responsibilities under the Act, or more specific information, such as additional guidance materials, may be obtained from the Division of Small Manufacturers, International and Consumers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597, or at its internet address, "dsmica@cdrh.fda.gov.

Sincerely yours,

Timothy A. Ulatowski
Director
Office of Compliance
Center for Devices and
Radiological Health

2

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
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Timothy A. Ulatowski
Director
Division of Dental, Infection Control
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Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Ver/ 3 - 4/24/96

Applicant: I-Flow Corporation

510(k) Number (if known): _____

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Adam Cicconetti

(Division Sign-Off)
Division of Dental, Infection Control,
and General Hospital Devices
510(k) Number K020251

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Per 21 CFR 801.109)

(Optional Format 1-2-96)

DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service
Food and Drug Administration

Date: 2/14/02

Memorandum

m: Reviewer(s) Name(s) Irene Naveau

Subject: 510(k) Number K020251

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

☐ Refused to accept.
☐ Requires additional information (other than refuse to accept).
☒ Is substantially equivalent to marketed devices.
☐ NOT substantially equivalent to marketed devices.
De Novo Classification Candidate? ☐ YES ☐ NO
☐ Other (e.g., exempt by regulation, not a device, duplicate, etc.)

Is this device subject to Postmarket Surveillance?	☐ YES	☒ NO
Is this device subject to the Tracking Regulation?	☐ YES	☒ NO
Was clinical data necessary to support the review of this 510(k)?	☐ YES	☒ NO
Is this a prescription device?	☒ YES	☐ NO
Was this 510(k) reviewed by a Third Party?	☐ YES	☒ NO
Special 510(k)?	☒ YES	☐ NO
Abbreviated 510(k)? Please fill out form on H Drive 510k/boilers	☐ YES	☒ NO

This 510(k) contains:
Truthful and Accurate Statement ☐ Requested ☒ Enclosed
(required for originals received 3-14-95 and after)
☒ A 510(k) summary OR ☐ A 510(k) statement
☐ The required certification and summary for class III devices
☒ The indication for use form (required for originals received 1-1-96 and after)
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: 80 | FPA | II | 880.5440

Additional Product Code(s) with panel (optional): 80 | FRN | II | 880.5725

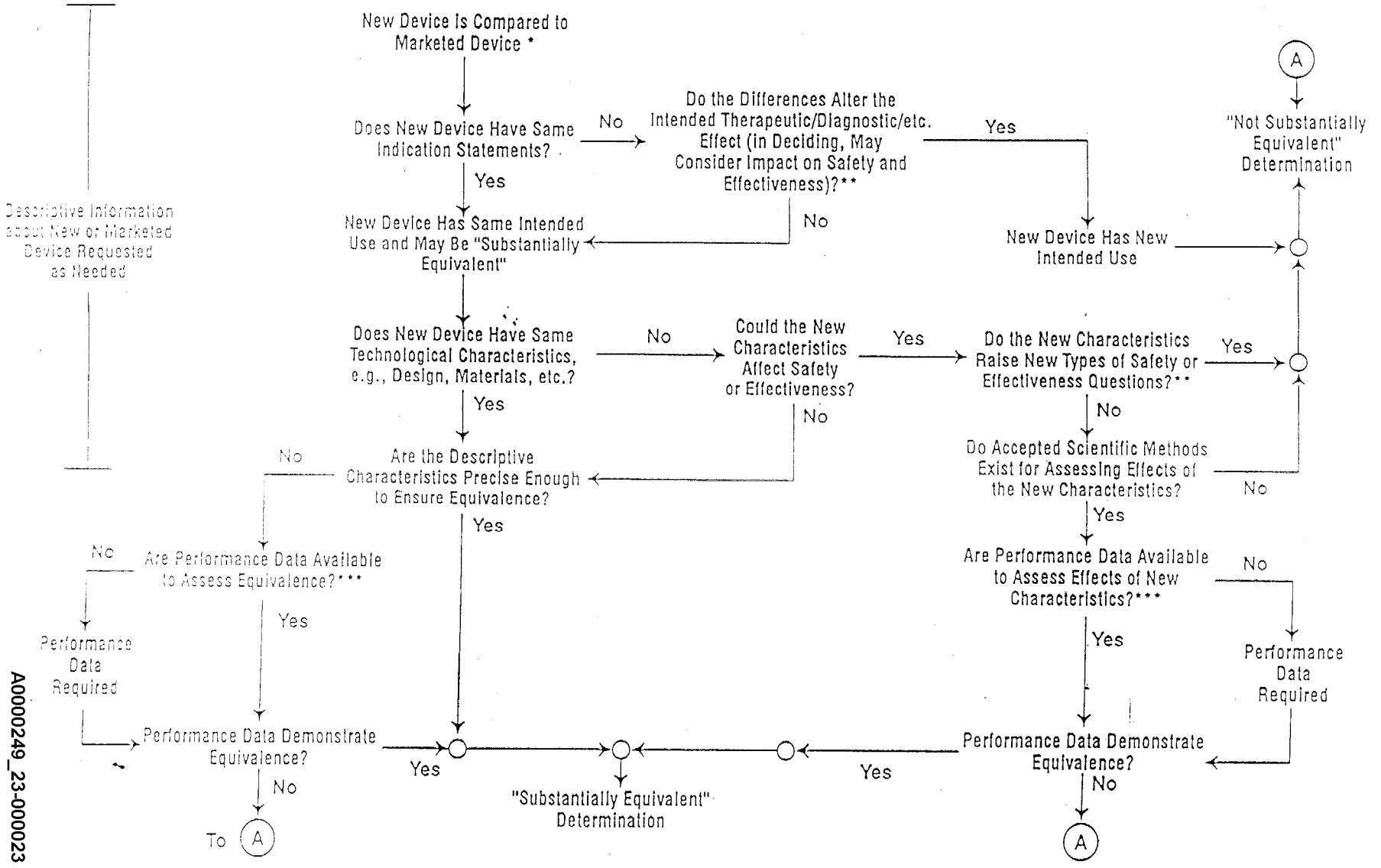
Review: Katherine Carrente (Branch Chief) — DRDB (Branch Code) — 2/15/02 (Date)

Final Review: (Division Director) — 2/15/02 (Date)

Revised:8/17/99

4

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



A0000249_23-000023

* 510(k) Submissions Compare New Devices to Marketed Devices. FDA Requests Additional Information If the Relationship Between Marketed and "Predicate" (Pre-Amendments or Reclassified Post-Amendments) Devices Is Unclear.

** This Decision Is Normally Based on Descriptive Information Alone, But Limited Testing Information Is Sometimes Required.

*** Data May Be In the 510(k), Other 510(k)s, The Center's Classification Files, or the Literature.

SPECIAL 510(k): Device Modification
ODE Review Memorandum

To: THE FILE **RE:** DOCUMENT NUMBER K020251; Paragon Infusion System

This 510(k) submission contains information/data on modifications made to the SUBMITTER'S own Class II devices requiring 510(k). The following items are present and acceptable:

1. The name and 510(k) number of the SUBMITTER'S previously cleared devices.
2. Submitter's statement that the **INDICATION/INTENDED USE** of the modified device as described in its labeling **HAS NOT CHANGED** along with the proposed labeling which includes instructions for use, package labeling, and, if available, advertisements or promotional materials.
3. A description of the device **MODIFICATION(S),** including clearly labeled diagrams, engineering drawings, photographs, user's and/or service manuals in sufficient detail to demonstrate that the **FUNDAMENTAL SCIENTIFIC TECHNOLOGY** of the modified device **has not changed.**

   This change was for a device modification that incorporates a variable flow rate component with

4. A **Design Control Activities Summary** which includes:
   a) Identification of Risk Analysis method(s) used to assess the impact of the modification on the device and its components, and the results of the analysis
   b) Based on the Risk Analysis, an identification of the verification and/or validation activities required, including methods or tests used and acceptance criteria to be applied
   c) A declaration of conformity with design controls. The declaration of conformity should include:
      i) A statement signed by the individual responsible, that, as required by the risk analysis, all verification and validation activities were performed by the designated individual(s) and the results demonstrated that the predetermined acceptance criteria were met, and
      ii) A statement signed by the individual responsible, that the manufacturing facility is in conformance with design control procedure requirements as specified in 21 CFR 820.30 and the records are available for review.
5. A **Truthful and Accurate Statement**, a **510(k) Summary or Statement** and the **Indications for Use Enclosure (and Class III Summary for Class III devices).**

The labeling for this modified subject device has been reviewed to verify that the indication/intended use for the device is unaffected by the modification. In addition, the submitter's description of the particular modification(s) and the comparative information between the modified and unmodified devices demonstrate that the fundamental scientific technology has not changed. The submitter has provided the design control information as specified in The New 510(k) Paradigm and on this basis, I recommend the device be determined substantially equivalent to the previously cleared (or their preamendment) device.

Irene Mavar
(Reviewer's Signature)

2/14/02
(Date)

Comments
Labeling was amended to

2/14/02
variable flow rate component.

revised:3/27/98

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

510(k) Number: K020251

The cover letter clearly identifies the type of 510(k) submission as (Check the appropriate box):

☑ Special 510(k) - Do Sections 1 and 2

☐ Abbreviated 510(k) - Do Sections 1, 3 and 4

☐ Traditional 510(k) or no identification provided - Do Sections 1 and 4

Section 1: Required Elements for All Types of 510(k) submissions:

	Present	Inadequate or Missing
Cover letter, containing the elements listed on page 3-2 of the Premarket Notification [510)] Manual.	✓	
Table of Contents.	✓	
Truthful and Accurate Statement.	✓	
Device's Trade Name, Device's Classification Name and Establishment Registration Number.	✓	
Device Classification Regulation Number and Regulatory Status (Class I, Class II, Class III or Unclassified).	✓	
Proposed Labeling including the material listed on page 3-4 of the Premarket Notification [510)] Manual.	✓	
Statement of Indications for Use that is on a separate page in the premarket submission.	✓	
Substantial Equivalence Comparison, including comparisons of the new device with the predicate in areas that are listed on page 3-4 of the Premarket Notification [510)] Manual.	✓	
510(k) Summary or 510(k) Statement.	✓	
Description of the device (or modification of the device) including diagrams, engineering drawings, photographs or service manuals.	✓	
Identification of legally marketed predicate device. *		
Compliance with performance standards. * [See Section 514 of the Act and 21 CFR 807.87 (d).]		
Class III Certification and Summary. **		
Financial Certification or Disclosure Statement for 510(k) notifications with a clinical study. * [See 21 CFR 807.87 (i)]		
510(k) Kit Certification ***		

* - May not be applicable for Special 510(k)s.
** - Required for Class III devices, only.
*** - See pages 3-12 and 3-13 in the Premarket Notification [510)] Manual and the Convenience Kits Interim Regulatory Guidance.

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

	Present	Inadequate or Missing
Name and 510(k) number of the sponsor's own, unmodified predicate device.		
A description of the modified device and a comparison to the sponsor's predicate device.		
A statement that the intended use(s) and indications of the modified device, as described in its labeling, are the same as the intended uses and indications for the sponsor's unmodified predicate device.		
A statement that the modification has not altered the fundamental technology of the sponsor's predicate device.		
A Design Control Activities Summary that includes the following elements (a-e):		
a. Identification of Risk Analysis method(s) used to assess the impact of the modification on the device and its components, and the results of the analysis.		
b. Based on the Risk Analysis, an identification of the required verification and validation activities, including the methods or tests used and the acceptance criteria to be applied.		
c. A Declaration of Conformity with design controls that includes the following statements:		
A statement that, as required by the risk analysis, all verification and validation activities were performed by the designated individual(s) and the results of the activities demonstrated that the predetermined acceptance criteria were met. This statement is signed by the individual responsible for those particular activities.		
A statement that the manufacturing facility is in conformance with the design control procedure requirements as specified in 21 CFR 820.30 and the records are available for review. This statement is signed by the individual responsible for those particular activities.		

Section 3: Required Elements for an ABBREVIATED 510(k)* submission:

	Present	Inadequate or Missing
For a submission, which relies on a guidance document and/or special control(s), a summary report that describes how the guidance and/or special control(s) was used to address the risks associated with the particular device type. (If a manufacturer elects to use an alternate approach to address a particular risk, sufficient detail should be provided to justify that approach.)		
For a submission, which relies on a recognized standard, a declaration of conformity [For a listing of the required elements of a declaration of conformity, SEE **Required Elements for a Declaration of Conformity to a Recognized Standard,** which is posted with the 510(k) boilers on the **H drive.**]		
For a submission, which relies on a recognized standard without a declaration of conformity, a statement that the manufacturer intends to conform to a recognized standard and that supporting data will be available before marketing the device.		
For a submission, which relies on a non-recognized standard that has been historically accepted by FDA, a statement that the manufacturer intends to conform to a recognized standard and that supporting data will be available before marketing the device.		
For a submission, which relies on a non-recognized standard that has not been historically accepted by FDA, a statement that the manufacturer intends to conform to a recognized standard and that supporting data will be available before marketing the device and any additional information requested by the reviewer in order to determine substantial equivalence.		
Any additional information, which is not covered by the guidance document, special control, recognized standard and/or non-recognized standard, in order to determine substantial equivalence.		

* - When completing the review of an abbreviated 510(k), please fill out an Abbreviated Standards Data Form (located on the H drive) and list all the guidance documents, special controls, recognized standards and/or non-recognized standards, which were noted by the sponsor.

Section 4: Additional Requirements for ABBREVIATED and TRADITIONAL 510(k) submissions (If Applicable):

	Present	Inadequate or Missing
a) Biocompatibility data for all patient-contacting materials, OR certification of identical material/formulation:		
b) Sterilization and expiration dating information:		
i) sterilization process		
ii) validation method of sterilization process		
iii) SAL		
iv) packaging		
v) specify pyrogen free		
vi) ETO residues		
vii) radiation dose		
c) Software Documentation:		

Items with checks in the "Present but Deficient" column require additional information from the sponsor. Items with checks in the " Missing" column must be submitted before substantive review of the document.

Passed Screening: ____Yes ____No
Reviewer: Irene Nauseda
Concurrence by Review Branch:_____
JAN 25 2002
Date:_____

The deficiencies identified above represent the issues that we believe need to be resolved before our review of your 510(k) submission can be successfully completed. In developing the deficiencies, we carefully considered the statutory criteria as defined in Section 513(i) of the Federal Food, Drug, and Cosmetic Act for determining substantial equivalence of your device. We also considered the burden that may be incurred in your attempt to respond to the deficiencies. We believe that we have considered the least burdensome approach to resolving these issues. If, however, you believe that information is being requested that is not relevant to the regulatory decision or that there is a less burdensome way to resolve the issues, you should follow the procedures outlined in the "A Suggested Approach to Resolving Least Burdensome Issues" document. It is available on our Center web page at: http://www.fda.gov/cdrh/modact/leastburdensome.html

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.	[redacted]	
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.		✓

REVISED:3/14/95

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

"SUBSTANTIAL EQUIVALENCE" (SE) DECISION MAKING DOCUMENTATION

K_____

Reviewer:_____

Division/Branch:_____

Device Name:_____

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

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

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

1. Intended Use:

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

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

1. Explain why not a device:

2. Explain why not subject to 510(k):

3. How does the new indication differ from the predicate device's indication:

4. Explain why there is or is not a new effect or safety or effectiveness issue:

5. Describe the new technological characteristics:

6. Explain how new characteristics could or could not affect safety or effectiveness:

7. Explain how descriptive characteristics are not precise enough:

8. Explain new types of safety or effectiveness questions raised or why the questions are not new:

9. Explain why existing scientific methods can not be used:

10. Explain what performance data is needed:

11. Explain how the performance data demonstrates that the device is or is not substantially equivalent:

ATTACH ADDITIONAL SUPPORTING INFORMATION

DEPARTMENT OF HEALTH AND HUMAN SERVICES Public Health Service

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

January 24, 2002

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

510(k) Number: K020251
Received: 24-JAN-2002
Product: PARAGON INFUSION SYSTEM

The Center for Devices and Radiological Health (CDRH), Office of Device Evaluation (ODE), has received the Premarket Notification you submitted in accordance with Section 510(k) of the Federal Food, Drug, and Cosmetic Act (Act) for the above referenced product. We have assigned your submission a unique 510(k) number that is cited above. Please refer prominently to this 510(k) number in any future correspondence that relates to this submission. We will notify you when the processing of your premarket notification has been completed or if any additional information is required. YOU MAY NOT PLACE THIS DEVICE INTO COMMERCIAL DISTRIBUTION UNTIL YOU RECEIVE A LETTER FROM FDA ALLOWING YOU TO DO SO.

As a reminder, we would like to mention that FDA requires all 510(k) submitters to provide an indications for use statement on a separate page. If you have not included this indications for use statement in addition to your 510(k) summary (807.92), or a 510(k) statement (807.93), and your Truthful and Accurate statement, please do so as soon as possible. If the above mentioned requirements have been submitted, please do not submit them again. There may be other regulations or requirements affecting your device such as Postmarket Surveillance (Section 522(a)(1) of the Act) and the Device Tracking regulation (21 CFR Part 821). Please contact the Division of Small Manufacturers, International and Consumer Assistance (DSMICA) at the telephone or web site below for more information.

Please remember that all correspondence concerning your submission MUST be sent to the Document Mail Center (DMC)(HFZ-401) at the above letterhead address. Correspondence sent to any address other than the DMC will not be considered as part of your official premarket notification submission. 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 DMC (HFZ-401).

You should be familiar with the manual entitled, "Premarket Notification 510(k) Regulatory Requirements for Medical Devices" available from DSMICA. If you have other procedural or policy questions, or want information on how to check on the status of your submission (after 90 days from the receipt date), please contact DSMICA at (301) 443-6597 or its toll-free number (800) 638-2041, or at their Internet address http://www.fda.gov/cdrh/dsmamain.html or me at (301) 594-1190.

Sincerely yours,

Marjorie Shulman
Consumer Safety Officer
Premarket Notification Staff
Office of Device Evaluation
Center for Devices and Radiological Health

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K020251

CDRH Submission Cover Sheet

Date of Submission: January 23, 2002

FDA Document Number:

Section A Type of Submission

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

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

Section B Applicant or Sponsor

Company / Institution name: I-Flow Corporation

Establishment registration number: 2026095

Division name (if applicable):

Phone number (include area code):

Street address: 20202 Windrow Drive

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

Contact name: Stanley E.

Contact title: Vice Preside

RECEIVED JAN 24 FDA/CDRH/OSB/DMPQ

Section C Submission correspondent (if different from above)

Company / Institution name: I-Flow Corporation

Establishment registration number: 2026095

Division name (if applicable):

Street address: 20202 Windrow Drive

City: State / Provin

Contact name: Shane Noehre, RAC

Contact title: Manager, Regulatory Affairs

Contact e-mail address:

SK 33 40

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

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

Section D2 — Reason for Submission — IDE

- ☐ New device
- ☐ Addition of institution
- ☐ Expansion / extension of study
- ☐ IRB certification
- ☐ Request hearing
- ☐ Request waiver
- ☐ Termination of study
- ☐ Withdrawal of application
- ☐ Unanticipated adverse effect
- ☐ Notification of emergency use
- ☐ Compassionate use request
- ☐ Treatment IDE
- ☐ Continuing availability request
- ☐ Other reason (specify):
- ☐ Change in:
  - ☐ Correspondent
  - ☐ Design
  - ☐ Informed consent
  - ☐ Manufacturer
  - ☐ Manufacturing process
  - ☐ Protocol – feasibility
  - ☐ Protocol – other
  - ☐ Sponsor
- ☐ Report submission:
  - ☐ Current investigator
  - ☐ Annual progress
  - ☐ Site waiver limit reached
  - ☐ Final
- ☐ Response to FDA letter concerning:
  - ☐ Conditional approval
  - ☐ Deemed approved
  - ☐ Deficient final report
  - ☐ Deficient progress report
  - ☐ Deficient investigator report
  - ☐ Disapproval
  - ☐ Request extension of time to respond to FDA
  - ☐ Request meeting

Section D3 — Reason for Submission — 510(k)

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

Section E — Additional Information on 510(k) Submissions

Product codes of devices to which substantial equivalence is claimed:

1 FRN	2 FPA	3 MEB	4 MEA
5	6	7	8

Summary of, or statement concerning, safety and effectiveness data:
- ☒ 510(k) summary attached
- ☐ 510(k) statement

Information on devices to which substantial equivalence is claimed:

510(k) Number	Trade or proprietary or model name	Manufacturer
1 K923875	1 Paragon Infusion System (originally SideKick Plus)	1 I-Flow Corporation
2 K984146	2 Paragon Infusion Kit	2 I-Flow Corporation
3 K984063	3 Paragon Basal with Bolus	3 I-Flow Corporation
4 K984638	4 Paragon Bolus Accessory	4 I-Flow Corporation
5 K960318	5 Rate Adjustable Ranger Infusion Device (originally DIB-Infusor-RA)	5 Novacon
6 K890489	6 Extension Set with Flow Regulator	6 Baxter

Section F — Product Information — Applicable to All Applications

Common or usual name or classification name:
Infusion Pump and Administration Sets

Trade or proprietary or model name	Model number
1 Paragon	1 various
2	2
3	3
4	4
5	5

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

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

Data included in submission: ☐ Laboratory testing ☐ Animal trials ☐ Human trials

Section G — Product Classification — Applicable to All Applications

Product code: FRN	C.F.R. Section: 880.5725	Device class: ☐ Class I ☒ Class II ☐ Class III ☐ Unclassified
Classification panel: General Hospital		

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

Note: Submission of this information does not affect the need to submit a 2891 or 2891a Device Establishment Registration form.	FDA Document Number:

Section H Manufacturing / Packaging / Sterilization Sites Relating to a Submission

☒ Original ☐ Add ☐ Delete	FDA establishment registration number: 2026095	☒ Manufacturer ☐ Contract manufacturer	☐ Contract sterilizer ☐ Repackager / relabeler
Company / Institution name: I-Flow Corporation		Establishment registration number: 2026095	
Division name (if applicable):			
Street address: 20202 Windrow Drive			
City: Lake Forest	State / Province: CA	Country: U.S.A.	
Contact nan			
Contact title: Manager, Regulatory Affairs		Contact e-mail address:	
☐ Original ☐ Add ☐ Delete	FDA establishment registration number:	☐ Manufacturer ☐ Contract manufacturer	☐ Contract sterilizer ☐ Repackager / relabeler
Company / Institution name:		Establishment registration number:	
Division name (if applicable):		Phone number (include area code): ( )	
Street address:		FAX number (include area code): ( )	
City:	State / Province:	Country:	
Contact name:			
Contact title:		Contact e-mail address:	
☐ Original ☐ Add ☐ Delete	FDA establishment registration number:	☐ Manufacturer ☐ Contract manufacturer	☐ Contract sterilizer ☐ Repackager / relabeler
Company / Institution name:		Establishment registration number:	
Division name (if applicable):		Phone number (include area code): ( )	
Street address:		FAX number (include area code): ( )	
City:	State / Province:	Country:	
Contact name:			
Contact title:		Contact e-mail address:	

SPECIAL 510(k): Device Modification

January 23, 2002

Via Federal Express

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

Reviewing Staff:

In accordance with §510(k) of the Federal Food, Drug, and Cosmetic Act and in conformance with Title 21 CFR §807.81, I-Flow Corporation is submitting this premarket notification for the *Paragon Infusion System* prior to the introduction into interstate commerce for commercial distribution.

I-Flow intends to market a new optional component for the Paragon administration sets. This new component is intended to allow variable flow rates.

The existing (unmodified) *Paragon Infusion System* has been cleared under the following 510(k)s: K923875, K984146, K984063 and K984638.

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

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

Shane Noehre
Manager of Regulatory Affairs

Sincerely,

/s/

Shane Noehre, RAC
Manager, Regulatory Affairs
I-Flow Corporation
20202 Windrow Dr
Lake Forest. CA 92630

TABLE OF CONTENTS

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 Quality of I-Flow Corporation, I believe to the best of my knowledge, that all data and information submitted in the premarket notification for the Paragon Infusion System are truthful and accurate and that no material fact has been omitted.

[illegible] and Quality

I-Flow Corporation 1/23/02
Company Dated

Premarket Notification (510(k) Number)

Ver/ 3 - 4/24/96

Applicant: I-Flow Corporation

510(k) Number (if known): _____

Device Name: Paragon Infusion System

Indications For Use:

1. The Paragon Infusion System is intended for continuous and/or intermittent infusion of medications for general infusion use, including antibiotic delivery, chemotherapy and pain management. Routes of administration include the following: intravenous, subcutaneous, intramuscular and epidural.
2. The Paragon Infusion System is also intended for continuous and/or intermittent delivery of medication (such as local anesthetics or narcotics) to surgical wound sites for postoperative regional anesthesia and pain management. Routes of administration may be intraoperative or percutaneous.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Per 21 CFR 801.109)

(Optional Format 1-2-96)

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DECLARATION OF CONFORMITY

As required by the risk analysis, all verification and validation activities will be performed by designated individuals and the results shall demonstrate that the predetermined acceptance criteria are met prior to the introduction into interstate commerce for commercial distribution.

The I-Flow Corporation manufacturing facilities are in conformance with the design control requirements as specified in 21 CFR 820.30 and the records are available for review.

Vice President of Regulatory and Quality
I-Flow Corporation

Vice President of Engineering / R&D
I-Flow Corporation

Verification and Validation activity will ensure the device meets the requisite design specifications and acceptance criteria and shall include the following:

1. Flow Rate Accuracy:
2. Leak Testing: no leaks when pressurized to
3. Residual Volume: <
4. Bond Strength: > external manifold tubes), >
   (flow control tubes).
5. Labeling: per section of this submission.
6. Package Integrity: per section of this submission.
7. Sterility: per section 12.0 of this submission.
8. Incoming Inspection: per the Risk Assessment.
9. Inprocess and Final Inspection: per the Risk Assessment.

Reference Documents

1. Risk Assessment f)

SPECIAL 510(K) - SUMMARY OF SAFETY AND EFFECTIVENESS

January 23, 2002

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

Contact: Shane Noehre
Manager of Regulatory Affairs
I-Flow Corporation

Trade Name: Paragon Infusion System

Common Name: Infusion Pump and Administration Set

Classification Name: Pump, Infusion

Existing Device: Paragon Infusion System (K923875, K984146, K984063, K984638)

Device Description: The Paragon Infusion System consists of a reusable mechanical infusion pump and various types of single use administration sets. This special 510(k) proposes a new line of administration sets that incorporates a variable flow rate mechanism.

Technology Comparison: The Paragon Infusion System with Variable Flow Rate utilizes the same technology for regulating flow rate (i.e. flow control tubing) and similar devices with variable flow rate components exist in the market (Novacon DIB-Infusor-RA – K960318 and Baxter Flow Regulator – K890489).

Conclusion: The Paragon Infusion System is substantially equivalent to the existing Paragon Infusion System and other variable flow rate devices currently being legally marketed.

1.0 GENERAL INFORMATION

1.1 Purpose of Submission

1.1.1 This submission is intended to notify the Federal Food and Drug Administration that I-Flow intends to make a device modification to our own legally marketed device. The change affects the Paragon administration sets of the *Paragon Infusion System*. A new optional component for the Paragon administration sets will incorporate a variable flow rate component.

1.1.2 The existing (unmodified) Paragon administration sets have been cleared under the following 510(K)s:

- K923875 – the initial Paragon premarket notification (originally identified as the SideKick Plus).
- K984146 – added intraoperative and percutaneous routes of administration, added the Y-adapter models, added convenience kit models.
- K984063 – added the basal with bolus models.
- K984638 – added the bolus only accessory model.

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

1.1.4 Common Name: Infusion Pump and Administration Set

1.1.5 Classification Name: Pump, Infusion

1.1.6 Product Code: FRN

1.1.7 Device Classification: Class II, 880.5725

1.1.8 Medical Specialty: General Hospital

2.0 PHYSICAL SPECIFICATIONS AND DESCRIPTONS

2.1 Description of Device

The Paragon Infusion System (

emarket notification proposes a new line of administration sets, i.e. No change will be made to the Paragon infusion pump.

2.2 The Paragon Pump

2.2.1 The Paragon pump c

2.2.2 The

(The load is applied to the (

2.2.3 The ɔ allow for positioning of the administration set.

2.2.4 When

2.3 The Paragon Administration Sets

See Appendix B for drawings.

2.3.1 The Paragon administration sets the administration line. The drug bag and administration line may be permanently bonded together or sold separately. The drug bag is filled with medication via a fill port. All Paragon administration sets are

sets may be used the Paragon pump or another infusion pump. The administration line may incorporate any of the following optional components:

2.3.1.1

Note: All these features with the exception of the variable flow component have been cleared in previous 510(k)s.

2.3.2 The Variable Flow Component:

2.3.2.1 This component has ɔan be selected from a dial. The dial is labeled with each flow rate and a "key" is used to rotate the dial from position to position. As a flow rate is dialed in, a tactile click can be felt. After the healthcare provider has selected the flow rate, the key may be removed and the dial cover is closed and tied off to prevent inadvertent changes to the flow rate.

See section **3.0** for model configurations.

2.3.2.2 The device

Dial Position	Microbore Tubing			Net Flow Rate (ml/hr)
	0.5 ml/hr	1.0 ml/hr	2.0 ml/hr	
OFF	OFF	OFF	OFF	

Thus the OFF p
When dialed to

2.4 **Flow Control**

2.4.1 The fundamental scientific technology for controlling the flow rate remains the same as the existing (unmodified) Paragon administration sets.

2.4.2 Each administration set consists of a

2.4.3 The
the F
rates

2.4.4 Where Q is the flow rate, ρ is the pressure drop a s the inside diameter of the flow controlling orifice, μ is the dynamic viscosity of the fluid and L tion provides an approximation

3.0 NEW MODELS

3.1 (optional) Variable Flow Rate Component

This optional component replaces
combination of flow rates to be selected by the healthcare provider. The following models will be available:

3.1.1 Model 1: combination

3.1.1.1

3.1.2 Model 2: combination o control tubing yields:

3.1.3 Model 3

4.0 COMPONENTS AND MATERIALS

Note: No changes in materials will be made to the Paragon infusion pump. All fluid path materials in the Paragon administration sets are in compliance with ISO 10993 prior to market distribution.

The Paragon infusion pump is re-usable. The Paragon administration sets are disposable and single use only.

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chemotherapy and pain manage

5.0 OPERATIONAL SPECIFICATIONS AND DESCRIPTIONS

5.1 **Standard Operating Conditions:**

Priming/Residual Volume: ~ 5 ml

Operating Temperature: or Variable Flow Rate set

Test Solution: nal saline

Operating Pressure: ssure source

Head Height:

Accuracy: 5% confidence interval

5.2 **Power Requirements:** The Paragon Infusion System is a mechanical device that nfusion pump for power. No additional external power source is required to operate.

5.3 **Safety/Alarm Functions**

5.3.1 The Paragon Infusion System provides fixed flow and as such is not subject to fluid runaway conditions similar to that of some electronic pumps.

5.3.2 If for any reason the patient needs to stop his or her infusions, each administration set is supplied with a pinch clamp to stop the infusion.

5.3.3 This device contains no alarms or indicators for flow other than visual except for the FlowView sets which contain a flow indicator.

5.3.4 This device contains no alarms or indicators to detect air in line; however, each set may include an integrated

6.0 BIOCOMPATIBILITY SPECIFICATIONS

6.1 Biocompatibility testing is in conformance with ISO 10993 Part 1 for all fluid path components based on intended application of the device prior to market distribution.

7.0 CHEMICAL AND DRUG SPECIFICATIONS

7.1 Compatibility

7.1.1 There are no specific drugs referenced in the labeling for the Paragon Infusion System.

7.1.2 The Paragon Infusion System is intended for general purpose drugs and pain medication.

7.2 Drug Stability

7.2.1 There are no specific drugs referenced in the labeling for the Paragon Infusion System.

8.0 INDICATIONS FOR USE

8.1 There is no change to indications for use.

8.2 The Paragon Infusion System is intended for continuous and/or intermittent infusion of medications for general infusion use, including antibiotic delivery, chemotherapy and pain management. Routes of administration include the following: intravenous, subcutaneous, intramuscular and epidural.

8.3 The Paragon Infusion System is also intended for continuous and/or intermittent delivery of medication (such as local anesthetics or narcotics) to surgical wound sites for postoperative regional anesthesia and pain management. Routes of administration may be intraoperative or percutaneous.

8.4 The Paragon infusion pump may be used multiple times. The Paragon administration sets are single use only.

8.5 The Paragon Infusion System is suitable for use as an ambulatory device and is intended for use in the hospital, home environment or alternative care sites.

9.0 LABELS AND LABELING

9.1 The only change to the labeling will be for clarification of use of the variable flow rate component.

9.2 I-Flow Corporation believes the proposed labels and labeling, where appropriate, meets the requirements of 21 CFR Part 801 as it relates to a determination of intended use and adequate directions for use.

9.3 The Paragon Infusion System Directions for Use labeling:

9.3.1 Provides comprehensive directions for preparation and use for the Paragon Infusion System.

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

9.3.3 Contains warning information.

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

9.3.5 Includes the specifications of the Paragon Infusion System. The specifications include the priming volume, residual volume, accuracy and operating conditions.

9.4 Identification labels and labeling

9.4.1 I-Flow has developed product identification labeling for the Paragon Infusion System. Refer to Appendix C for examples.

9.5 Packaging labels

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

10.0 STANDARDS

10.1 There are currently no standards established for mechanical infusion devices.

11.0 PACKAGING

11.1 There is no change in the packaging. Packaging is in conformance with the standard EN 868-1 (Packaging Materials and Systems for Medical Devices which are to be Sterilized).

11.2 The Paragon Infusion System is packaged in a

11.3 Packaging is

11.4 Package agir
|
package the
years.

12.0 STERILIZATION

12.1 There is no change in the sterilization methods.

12.2 The methods of sterilization

12.3 Sterilization validation metho

12.3.1

12.4 Sterilization validation methodology is

12.4.1

12.4.2 The maximum

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

12.6 The Paragon Infusion System is labeled pyrogen fre

12.6.1 I-Flow products have been validated fo

12.6.2 Either method may be used as necessary.

13.0 COMPARISON TO THE EXISTING (UNMODIFIED) PARAGON ADMINISTRATION SETS

13.1 Intended Use

13.1.1 No change in intended use.

13.2 Fundamental Scientific Technology

13.2.1 No change in technology.

13.2.2 The Paragon Infusion System is identical to the existing Paragon Infusion System with the exception of the variable flow component. The variable flow component utilizes the same technology for controlling the flow rate as other Paragon administration sets (

13.3 Operational Specifications

13.3.1 No change in specification other than

13.3.2 The operational specifications for the variable flow rate sets are the same as the existing (unmodified) Paragon Infusion System except for the The variable flow rate sets are calibrated at room temperature and the existing (unmodified) low flow rate Paragon sets are calibrated at

13.4 No change in sterilization or packaging.

Appendix A

Page(s) 000050 to 000054

Is(Are) exempted pursuant to

of the Freedom of Information Act

Appendix B

Page(s) 000056 to 000057

Is(Are) exempted pursuant to

of the Freedom of Information Act

Appendix C

I-FLOW®

REF PGV005-035
PART NO. 5001330

(12) Paragon® Variable Rate Administration Sets

0.5 ml/hr – 3.5 ml/hr

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

Manufactured by:
I-Flow Corporation
Lake Forest, CA 92630 U.S.A.
www.i-flowcorp.com

CE 0123

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

Assembled in Mexico

U.S. Patents: 6,251,098; U.S. and Foreign Patents Pending.

1302958A

REF PGV005-035
PART NO. 5001330

(1) Paragon® Variable Rate
Administration Set
0.5 ml/hr – 3.5 ml/hr

STERILE R LOT

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

Manufactured by:
I-Flow Corporation
Lake Forest, CA 92630 U.S.A.
www.i-flowcorp.com
Assembled in Mexico

CE 0123

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

U.S. Patents: 6,251,098; U.S. and Foreign Patents Pending.

1302957A

REF PGV010-070
PART NO. 5001331

(12) Paragon® Variable Rate Administration Sets

1.0 ml/hr – 7.0 ml/hr

STERILE R LOT

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

Manufactured by:
I-Flow Corporation
Lake Forest, CA 92630 U.S.A.
www.i-flowcorp.com
Assembled in Mexico

CE 0123

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

U.S. Patents: 6,251,098; U.S. and Foreign Patents Pending.

1302960A

REF PGV010-070
PART NO. 5001331

(1) Paragon® Variable Rate
Administration Set
1.0 ml/hr – 7.0 ml/hr

STERILE R LOT

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

Manufactured by:
I-Flow Corporation
Lake Forest, CA 92630 U.S.A.
www.i-flowcorp.com
Assembled in Mexico

CE 0123

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

U.S. Patents: 6,251,098; U.S. and Foreign Patents Pending.

1302959A

REF PGV020-140
PART NO. 5001332

(12) Paragon® Variable Rate
Administration Sets
2.0 ml/hr – 14.0 ml/hr

STERILE R LOT

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

Manufactured by:
I-Flow Corporation
Lake Forest, CA 92630 U.S.A.
www.i-flowcorp.com
Assembled in Mexico

CE 0123

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

U.S. Patents: 6,251,098; U.S. and Foreign Patents Pending. 1302982A

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I-FLOW®

REF PGV020-140
PART NO. 5001332

(1) Paragon® Variable Rate
Administration Set
2.0 ml/hr – 14.0 ml/hr

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

Manufactured by:
I-Flow Corporation
Lake Forest, CA 92630 U.S.A.
www.i-flowcorp.com
Assembled in Mexico

CE 0123

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

U.S. Patents: 6,251,098; U.S. and Foreign Patents Pending.

1302981A

Models: PGV005-035, PGV010-070, PGV020-140

PARAGON®
Drug Delivery System with Variable Rate Administration Set

Manufactured by:
I-Flow Corporation
Lake Forest, CA 92630
U.S.A.

CE 0123

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

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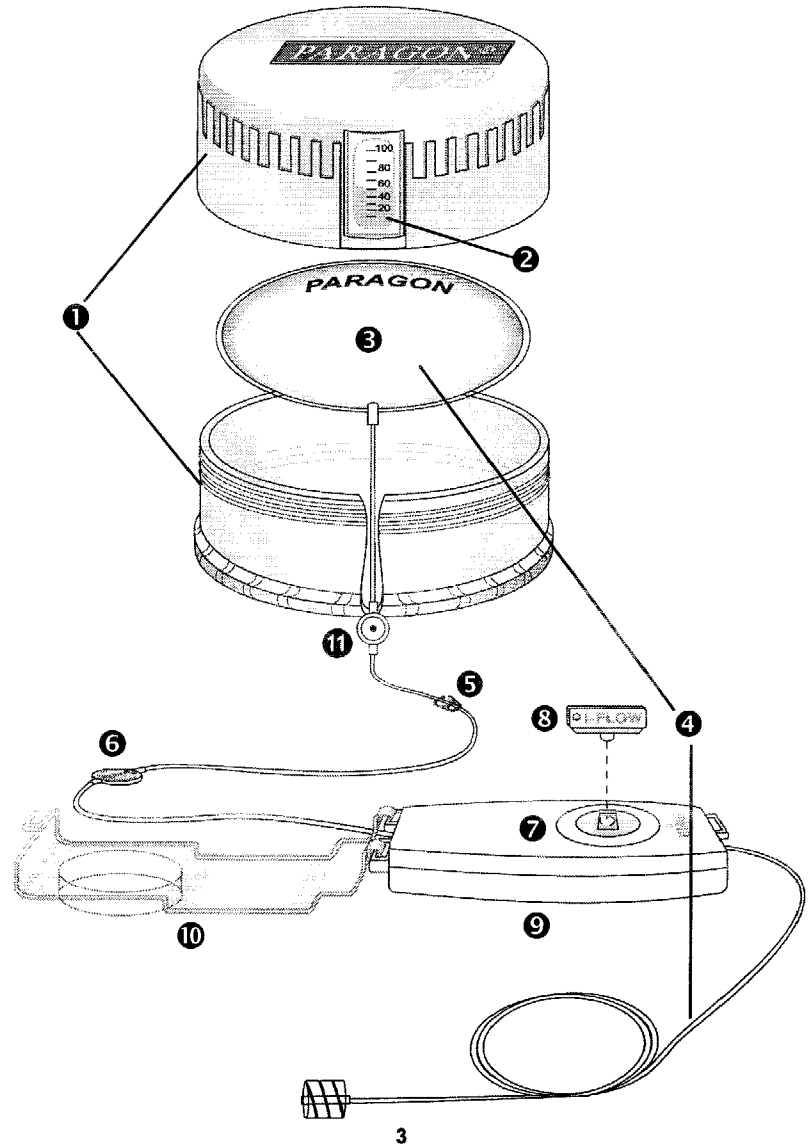

PARAGON®
Drug Delivery System with
Variable Rate Administration Set

ENGLISH

PARAGON®
Drug Delivery System with
Variable Rate Administration Set

GERMAN

PARAGON®
Drug Delivery System with
Variable Rate Administration Set

DUTCH

PARAGON®
Drug Delivery System with
Variable Rate Administration Set

FRENCH

PARAGON®
Drug Delivery System with
Variable Rate Administration Set

ITALIAN

PARAGON®
Drug Delivery System with
Variable Rate Administration Set

SPANISH

English

ENGLISH

PARAGON® Drug Delivery System
VARIABLE RATE ADMINISTRATION SET

DIRECTIONS FOR USE

NOMENCLATURE

1. *PARAGON* Infusion Pump, top and bottom
2. Fluid Level Indicator
3. Medication Bag
4. *PARAGON* Variable Rate Administration Set
5. Pinch Clamp
6. Filter 1.2 micron, air-eliminating
7. Flow Rate Dial
8. Rate-Changing Key
9. Variable Rate Controller
10. Lockable Cover
11. Fill Port

INDICATIONS FOR USE

The *PARAGON* Variable Rate Administration Set incorporates a controller that allows the user to adjust the infusion rate by turning the rate-changing key on the device. The flow rate is within a predetermined range and is designated on each device.

The *PARAGON* Variable Rate Administration Set is intended for use with the *PARAGON* Infusion Pump. The *PARAGON* Pump is a reusable mechanical pump that provides precise drug delivery of medications for general infusion use, including chemotherapy and pain management. Routes of administration include intravenous, subcutaneous, intramuscular and epidural.

CAUTIONS

1. Do not use if the package has been opened or is damaged or if either protector cap is not in place.
2. Device is initially set at mazimum flow rate. Adjust as necessary.
3. If the Variable Flow Rate Set is to be used for epidural drug administration, it should be labeled to differentiate from other routes of administration. Do not use a Y-adapter for epidural delivery. When using this administration set for epidural drug delivery, make certain only drugs recommended for this route of administration are used.
4. Do not resterilize the administration set. Administration sets are intended for single use only. The fluid pathway is sterile and nonpyrogenic. It is recommended that the administration set be changed in accordance with CDC guidelines or institutional policies.
5. **CAUTION:** Federal (U.S.A.) law restricts this device to sale by or on the order of a physician.

CONTRAINDICATION

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

FILLING THE *PARAGON* MEDICATION BAG

CAUTION: Use Aseptic Technique

1. Remove the medication bag with the attached Variable Rate Administration Set from its package.
2. Move the flow clamp next to the filling valve and close the clamp.
3. Fill a sterile syringe with the solution to be dispensed into the

medication bag.

4. Connect the tip of the syringe to the filling valve and inject the solution into the medication bag. Refill the syringe and repeat if necessary.

   Note: The *PARAGON* Pump is designed to hold a total of 100 ml of fluid. The maximum fill volume is 121 ml. If the amount of fluid exceeds 121 ml, it may be difficult to engage the threads on the top and bottom of the *PARAGON* Pump.

5. Remove the air from the medication bag by aspirating with a syringe attached to the filling valve. Squeezing the sides of the bag when pulling back on the syringe will aid in removing the air.
6. Replace the cap on the filling valve.

   Note: Do not place labels on the medication bag. Labels may be wrapped around the set.

LOADING THE MEDICATION BAG INTO THE *PARAGON* PUMP

1. Twist open the top and bottom halves of the *PARAGON* Pump.
2. Before placing the medication bag into the pump, slide the upper portion of the tubing on the administration set through the slot on the bottom of the pump.
3. Center the bag on the bottom and press around the edge of the bag to fully seat the bag on the bottom. Make sure there are no wrinkles in the bag.
4. Pull gently on the tubing so that it is fully extended and seated at the bottom of the slot.
5. Twist the top and bottom halves of the *PARAGON* Pump together until they fully engage.

PRIMING THE VARIABLE RATE ADMINISTRATION SET

Use Aseptic Technique

1. Open the plastic cover and ensure the dial on the face of the device is at the highest flow rate setting. Make sure you feel or hear the dial "click" into place and the selected flow rate is aligned below the ml/hr mark on the controller.
2. Open the clamp and remove the cap from the luer lock at the end of the set.
3. Medication will flow toward the end of the set.
4. When all air has been removed from the set and fluid is observed at the end of the luer lock, turn the dial to the OFF position and replace the cap on the end of the administration set.

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

STARTING THE INFUSION

1. Connect the administration set to the patient's catheter. Make sure the connection is secure.
2. Select the appropriate flow rate by turning the dial on the Controller until the dial clicks into place, and the flow rate setting is aligned with the ml/hr mark on the face of the Controller.

CAUTION: Insure proper flow rate is dialed.

WARNING: To discourage tampering, remove the rate-changing key from the dial by pulling the key straight out. Put the key in a safe place for later use, e.g., attached to a key ring.

Close the cover over the Variable Rate Controller. For increased tamper resistance, the cover may be locked to the Controller using a standard tie wrap.

Note: If desired, the cover may also be removed from the Variable Rate Controller by fully opening the cover and then pulling straight up on the plastic feet at the bottom of the cover.

CHANGING THE FLOW RATE DURING AN INFUSION

1. Insert the rate-changing key into the dial.
2. Turn the dial until the new flow rate is selected. Make sure you hear the dial "click" into place and the selected flow rate is aligned below the ml/hr mark on the Controller.
3. Remove the key from the dial and put in a safe place for later use.

THE FLUID LEVEL INDICATOR

1. The window with the graduated markings on the side of the *PARAGON* Pump is used to estimate how far the infusion has progressed.
2. When the *PARAGON* medication bag is filled to its capacity, the top of the pressure plate will be aligned with the top marking.
3. As the infusion progresses, the plate will move to the bottom marker indicating the bag is nearly empty.

THE END OF THE INFUSION

The infusion is complete when at least three (out of six) small blue dots appear through the bottom of the *PARAGON* Pump.

The Carrying Case

1. Place the *PARAGON* Pump in the carrying case so that the bottom of the pump can be seen through the clear plastic window.
2. Lift the Velcro strap and slide the administration set down so that the set exits the carrying case at the side window opening.

Secure the strap. Positioning the pump in this way allows for the viewing of the fluid level indicator

3. The front flap of the carrying case lifts up to reveal a clear plastic window, allowing for the viewing of the bottom of the pump to determine when the end of infusion has occured. At least three blue dots out of six appear.

4. If necessary, a small lock may be placed through the larger of the two holes on the zipper, and through the cloth loop on the side of the carrying case. (This may discourage tampering with the pump during an infusion.)

CARE OF THE *PARAGON*

The *PARAGON* Pump is durable and is intended to be used for repeated drug deliveries. After each patient use, the exposed surfaces, except the threads, may be wiped clean using isopropyl alcohol or a 10% bleach solution.

Note: Do not submerge the *PARAGON* Pump in a bleach solution. After cleaning, if the pump is difficult to twist together, place a small drop of lubricating ointment on a small section of the threads on the bottom of the pump. Twist the top of the pump onto the bottom to spread out the ointment.

IMPORTANT

1. This product uses DEHP-plasticized PVC. Certain solutions may be incompatible with the PVC material used in the *PARAGON* Variable Rate Administration Set. Consult the drug package insert and other available sources of information for a more through understanding of possible incompatibility problems.

2. Only administration sets manufactured 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 misuse of this product when used with unauthorized administration sets.

THE *PARAGON* VARIABLE RATE ADMINISTRATION SET SPECIFICATIONS

Flow Rates: Three different color-coded Variable Rate Administration sets are available with the following flow rate range:

- White - 2, 4, 6, 8, 10, 12, 14 ml/hr
- Green - 1, 2, 3, 4, 5, 6, 7 ml/hr
- Blue - 0.5, 1, 1.5, 2, 2.5, 3, 3.5 ml/hr

Delivery Accuracy: Flow rate accuracy is ± 10% at a 95% confidence interval.

Residual Volume: 5 ml or less

THE *PARAGON* PUMP SPECIFICATIONS

Size: 5.8 cm high; 10.2 cm in diameter

Weight: 260 g

CAUTIONS

Actual infusion 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 Pump above or below the catheter site.

The *PARAGON* Variable Flow Rate Set has been calibrated using Normal Saline (NS) as the diluent and room temperature (21°C, 72°F) as the operating environment. When using NS and room temperature the *PARAGON* System will flow at the specified nominal rate.

The use of other diluent or operating temperatures other than the above will affect the nominal flow rate. For example, if 5% dextrose (D5W) is used as the final diluent, the *PARAGON* System will flow at 10% below the nominal rate due to higher solution viscosity.

SpinalSpecialties, Inc.
An I-FLOW company

ENGLISH

For more information about this system visit our web site or call:

Within the USA:
800.678.6066

Outside the USA or for I-Flow Corporation:
800.448.3569
949.206.2700

www.i-flowcorp.com
www.spinalspecialties.com

Appendix D

CDRH Premarket Notification

U.S. Food and Drug Administration - Center for Devices and Radiolo

Other | 510(K) | Listing | MAUDE | PMA | Classification

disclaimer | site map | more 510(K) information | ab

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Device Classification Name	PUMP, INFUSION
Regulation Number	880.5725
510(k) Number	K923875
Device Name	SIDEKICK 50 PLUS AND SIDEKICK 100 PLUS
Applicant	I-FLOW CORP. 2532 WHITE ROAD IRVINE, CA 92714
Contact	ROBERT J BARD
Product Code	FRN
Date Received	08/03/1992
Decision Date	05/13/1993
Decision	SUBSTANTIALLY EQUIVALENT (SE)
Classification Advisory Committee	General Hospital
Review Advisory Committee	General Hospital
Statement/Summary/Purged Status	Summary/purged 510(k)
Type	Traditional
Reviewed by Third Party	No

(Database Updated November 5, 2001)

Accessibility

CDRH Products Classification

U.S. Food and Drug Administration - Center for Devices and Radiolog

Other | 510(K) | Listing | MAUDE | PMA | Classification | R

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Device	PUMP, INFUSION
Medical Specialty	General Hospital
Product Code	FRN
Device Class	2
510(k) Exempt?	No
Regulation Number	880.5725
Third Party Review	Eligible for *Mutual Recognition Agreement Program* Eligible for *Accredited Persons Program*

Accredited Persons and Third Party Program Information

Accredited Persons

- BRITISH STANDARDS INSTITUTION
- CALIFORNIA DEPARTMENT OF HEALTH SERVICES
- CENTER FOR MEASUREMENT STANDARDS OF INDUSTRIAL
- CITECH
- ENTELA, INC.
- INTERTEK TESTING SERVICES
- N.V. KEMA
- TUV PRODUCT SERVICE, INC.
- TUV RHEINLAND OF NORTH AMERICA, INC.
- UNDERWRITERS LABORATORIES, INC.

(Database Updated October 12, 2001)

Accessibility

[Code of Federal Regulations]
[Title 21, Volume 8]
[Revised as of April 1, 2001]
From the U.S. Government Printing Office via GPO Access
[**CITE: 21CFR880.5725**]

[Page 385-386]

TITLE 21--FOOD AND DRUGS

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

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

Subpart F--General Hospital and Personal Use Therapeutic Devices

Sec. 880.**5725** Infusion pump.

(a) Identification. An infusion pump is a device used in a health care facility

[[Page 386]]

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

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

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: K984146
Trade Name: Paragon Infusion
Regulatory Class: II
Product Code: FPA
Dated: November 11, 1998
Received: November 19, 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): K984146

Device Name: Paragon Infusion Kit

Indications for Use:

1. The Paragon Infusion Kit is intended to provide continuous infusion a local anesthetic directly into an intraoperative (soft tissue / body cavity) site for general surgery for postoperative pain management. Additional routes of administration include percutaneous, subcutaneous, intramuscular and epidural infusion.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Dental, Infection Control,
and General Hospital Devices
510(k) Number K984146

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

(Optional Format 1-2-96)

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

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: K984063
Trade Name: Paragon Basal/Bolus Administration Set
Regulatory Class: II
Product Code: FPA
Dated: November 11, 1998
Received: November 16, 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): K984063

Device Name: Paragon Basal/Bolus Administration Set

Indications for Use:

1. The Paragon Basal/Bolus Administration Set is intended to provide a continuous, basal level infusion of medication and to allow patient controlled bolus delivery. The bolus component of the administration set enables fixed boluses of medication to be delivered upon demand by the patient or healthcare provider. The Paragon Basal/Bolus Administration Set routes of administration include: 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 X OR Over-The-Counter Use
(Per 21 CFR 801.109)

(Optional Format 1-2-96)

(Division Sign-Off)
Division of Dental, Infection Control,
and General Hospital Devices
510(k) Number K984063

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)

Patricia Cucuzzella
(Division Sign-Off)
Division of Dental, Infection Control,
and General Hospital Devices
510(k) Number K984638

OR Over-The-Counter Use

(Optional Format 1-2-96)