

FEB 15 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.



Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

FEB 15 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.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

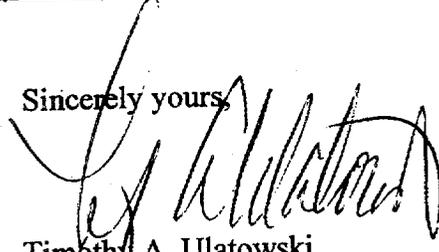
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies.

You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

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

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4618. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address <http://www.fda.gov/cdrh/dsma/dsmamain.html>

Sincerely yours,



Timothy A. Ulatowski  
Director

Division of 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

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.

*Anna Ciccenti*

(Division Sign-Off)

Division of Dental, Infection Control,  
and General Hospital Devices

510(k) Number

1020251

(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)