4/23/99

I-FLOW
CORPORATION

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K990425

SUMMARY OF SAFETY AND EFFECTIVENESS

February 9, 1999

Trade Name: SideKick Infusion Kit

Common Name: Infusion Pump Kit

Classification Name: Pump, Infusion

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

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

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

Telephone: 949.206.2700
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1.0 GENERAL INFORMATION

1.1 Purpose of Submission

1.1.1 This submission is intended to notify the Federal Food and Drug Administration that I-Flow Corporation intends to market a new kit, the SideKick Infusion Kit.

1.1.2 Trade Name: SideKick Infusion Kit

1.1.3 Common Name: Infusion Pump Kit

1.1.4 Classification Name: Pump, Infusion

1.1.5 Classification Panel: General Hospital and Personal Use Device

1.2 Statement of Equivalence

1.2.1 The SideKick Infusion Kit includes components that are legally marketed (either pre-amendment devices or devices that have been granted permission to market via premarket notification regulation).

1.2.2 The SideKick Kit is substantially equivalent to the I-Flow Paragon Infusion Kit (K984146), the I-Flow Paragon Infusion System (K923875), the I-Flow PainBuster Infusion Kit (K980558, K982946), the Sgarlato Pain Control Infusion Pump (PCIP) (K896422), the I-Flow Homepump C-Series (K944692) and the McKinley Outbound Disposable Syringe Infuser (K982256).

2.0 PHYSICAL SPECIFICATIONS AND DESCRIPTIONS

2.1 Description of the SideKick Infusion Kit

2.1.1 The SideKick Infusion Kit is identical to the I-Flow Paragon Infusion Kit with the exception of the SideKick pump and administration set replacing the Paragon pump and administration set.

2.1.2 The kit is comprised of a SideKick pump and administration set and various kit components such as catheter, needle, syringe, Y adapter, dressing, tape, gauze and carry case.

2.1.2.1 The Paragon Infusion Kit contains all the above components except for a Paragon pump and administration set instead of the SideKick pump and administration set.

2.1.3 The SideKick administration set is intended to attach to the kit catheter at the distal end of the set to provide continuous infusion of a local anesthetic directly into the intraoperative site for general surgery for postoperative pain management.

2.1.4 The SideKick administration set is a disposable device intended for single patient use. The SideKick pump is reusable.

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

2.2 Product Configuration

2.2.1 The SideKick Infusion Kit models are available in 100 ml fill volumes with 1 or 2 ml/hr flow rates.

2.2.2 Each model consists of a SideKick administration set with the following optional components/accessories:

2.2.2.1 SideKick pump, catheter, needle, syringe, dressing, carry case, antiseptic skin swabs, tape, gauze and Y adapter.

2.3 **Components and Materials**

All fluid path components of the SideKick administration set are identical to the fluid path components of the Paragon administration set.

2.4 **Power Requirements**

2.4.1 The SideKick pump is a mechanical pump that utilizes spring energy for power. No additional external power source is required.

3.0 OPERATIONAL SPECIFICATIONS AND DESCRIPTIONS

3.1 **Standard Operating Conditions:**

Residual Volume:	< 5 ml
Operating Temperature:	31°C skin temperature (90°F)
Test Solution:	0.9% NaCl
Operating Pressure:	9 to 1 psi pressure source
Head Height:	0"
Accuracy:	±15% at 95% confidence interval

3.2 **Flow Rate Performance Data**: Testing occurred at standard operating conditions. All models produced an average flow rate within the ±15% accuracy claim.

3.3 **Safety / Alarm Functions**

3.3.1 The SideKick pump and administration set provide a continuous fixed flow and as such is not subject to fluid runaway conditions similar to that of some electronic pumps.

4.0 BIOLOGICAL SPECIFICATIONS

4.1 Biological testing is in conformance with ISO 10993 Part 1 for all fluid path components of the SideKick administration set.

5.0 CHEMICAL AND DRUG SPECIFICATIONS

5.1 Compatibility

5.1.1 There are no specific drugs referenced in the labeling for the SideKick Infusion Kit.

5.1.2 The SideKick Infusion Kit is intended for use with general local anesthetics and epidural medications.

6.0 INTENDED USE

6.1 The SideKick Infusion Kit is intended to provide continuous infusion of a local anesthetic directly into an intraoperative (soft tissue / body cavity) site for general surgery for postoperative pain management.

6.2 Additional routes of administration include percutaneous, subcutaneous, intramuscular and epidural infusion.

6.3 The SideKick pump is re-usable. The disposable SideKick administration set is single patient use only.

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

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

7.0 PACKAGING

7.1 Packaging is suitable for either radiation or ETO sterilization.

8.0 STERILIZATION INFORMATION

8.1 The method of sterilization is ETO gas.

9.0 COMPARISON TO LEGALLY MARKETED DEVICES

9.1 The SideKick Infusion Kit has similar routes of administration and components as the following predicate devices: the Paragon Infusion Kit, the Paragon Infusion System, PainBuster Infusion Kit, Sgarlato Pain Control Infusion Pump (PCIP), Homepump C-Series and McKinley Outbound Syringe Infuser.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

APR 23 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: K990425
Trade Name: SideKick Infusion Kit
Regulatory Class: II
Product Code: FRN
Dated: February 9, 1999
Received: February 11, 1999

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

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CORPORATION

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510(k) Number (if known): _____

Device Name: SideKick Infusion Kit

Indications for Use:

1. The SideKick Infusion Kit is intended to provide continuous infusion of 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 K990425

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

(Optional Format 1-2-96)