MAR 2 7 2002

K020881

7.0 510(K) SUMMARY

Submitters name:

Science Incorporated
12150 Nicollet Avenue South
Burnsville, MN 55337
(952) 835-1333 (general)
(952) 646-2340 (direct)
(952) 835-1716 (fax)
Contact person: Lynn S. Weist, Vice President, Quality Assurance / Regulatory Affairs

Device name:	Proprietary name:	To be determined (in this document, the device is referred to as the **Science Incorporated Personal Infusor Local Pain Management Procedural Kit** or **Express**)
	Common name:	Elastomeric pump
	Classification name:	Infusion pump
Predicate device:	**Science Incorporated Personal Infusor Local Pain Management Procedural Kit** manufactured by Science Incorporated (K010824)	

Device description:

The **Science Incorporated Personal Infusor Local Pain Management Procedural Kit** consists of a **Personal Infusor** provided in a kit with medical device components including a catheter set, catheter introducer, 60 mL syringe, dressings and accessories. Each of the additional medical device components is purchased in finished form and is packaged with the **Personal Infusor** in the **Personal Infusor Local Pain Management Procedural Kit**.

The **Personal Infusors** provided in the **Personal Infusor Local Pain Management Procedural Kit** will be offered in three volume / flow rate configurations.

Personal Infusor Configurations

Volume	Delivery Time	Flow Rate
50 mL	96 hours (labeled maximum)	0.5 mL/hr
100 mL	96 hours (labeled maximum)	1.0 mL/hr
100 mL	50 hours	2.0 mL/hr

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 2 7 2002

Ms. Lynn Weist
Vice President, QA/RA
Science Incorporated
12150 Nicollet Avenue South
Burnsville, Minnesota 55337-1647

Re: K020881
Trade/Device Name: Personal Infusor Local Pain Management Procedural Set
Regulation Number: 880.5725
Regulation Name: Infusion Pump
Regulatory Class: II
Product Code: MEB
Dated: March 16 ,2002
Received: March 18, 2002

Dear Ms. Weist:

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) 594-4613. 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

Science Incorporated
12150 Nicollet Avenue South
Burnsville, MN 55337-1647

510(k) Number: K020881

Device Name: Science Incorporated Personal Infusor Local Pain Management Procedural Kit

Indications for Use:

The **Science Incorporated Personal Infusor Local Pain Management Procedural Kit** is intended to provide continuous infusion of physician-prescribed local anesthetic medications directly into the intraoperative site of a patient for management of postoperative pain. Medication is delivered percutaneously, through the infusor's administration line, which is attached to a catheter.

The **Personal Infusor** is portable and is suitable for use by ambulatory patients.

The **Personal Infusor** is intended for single use only.

The **Personal Infusor** is not intended for rapid infusion, intravenous or intra-arterial drug infusion, for the delivery of blood, blood products, lipids, or fat emulsions, or for use by patients with a history of allergic reactions to anesthetics.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use_____ OR Over-The Counter Use_____
(Per 21 CFR 801.109)

(Optional Format 1-2-96

(Division Sign-Off)
Division of Dental, Infection Control,
and General Hospital Devices
510(k) Number K020881