3/25/99

K990208

8.0 SUMMARY OF SAFETY AND EFFECTIVENESS

Submitters name:

Science Incorporated
7760 France Avenue South, Suite 1060
Bloomington, MN 55435
(612)835-1333
(612)835-1716 (fax)
Contact person: Ralph E. Hogancamp, Director of Quality and Regulatory Affairs

Device name: Proprietary name: To be determined

Common name: Elastomeric pump

Classification name: Infusion pump

Predicate devices: **Science Incorporated Personal Infusor (510 number K971362)**

Device description:

The **Science Incorporated PDS Personal Infusor with Drug Disposal Septal Port** is a self-contained, low-profile, disposable infusion device intended for the ambulatory delivery of physician-prescribed parenteral medications to patients. Its design engages three principle elements: a substrate base with molded ullage, a stored energy elastomeric film, and a preset rate control component with filter. Fluid medicaments are delivered to a patient via an attached 36-inch tubing set that adjoins a preexisting venous access site. The unit has a septal port which allows easy removal of unused medications to allow for proper disposal of both device and medication. The unit is disposable following a single use and features a novel visual flow status indicator that facilitates patient monitoring. The pump will be available in multiple volume/flow rate configurations, and prototype models have demonstrated unsurpassed accuracy and consistency of fluid flow over a broad gamut of operating temperatures and with solutions of widely varying viscosities. It has a drug disposal septal port for proper disposal of the unused drug per normal hospital practice.

Intended use:

The **PDS Personal Infusor with Drug Disposal Septal Port** is intended for the ambulatory infusion of physician-prescribed parenteral medications. The device will

be filled and prepared for administration by pharmacists, and administered by eligible patients and providers who have been trained in the pump's operation.

The flexibility offered by the device design will enable physicians to select from a variety of fluid flow rates and drug concentrations, and will provide clinicians and patients with a convenient and efficient option for the administration of beneficial drugs to patients.

Technological characteristics:

The **PDS Personal Infusor with Drug Disposal Septal Port** is technologically identical to the **Science Incorporated Personal Infusor** except for the addition of the drug disposal septal port.

Performance data:

The **Science Incorporated PDS Personal Infusor with Drug Disposal Septal Port** exhibits equivalent flow performance when compared to the predicate device. In our studies, the new devices displayed linearity of ±10% over a temperature range of 10-40° C when used with various diluents

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 25 1999

Mr. Ralph E. Hogancamp
Director of Quality and Regulatory Affairs
Science, Incorporated
7760 France Avenue South, Suite 1060
Bloomington, Minnesota 55435

Re: K990208
Trade Name: Personal Infusor with Drug Disposal Septal Port
Regulatory Class: II
Product Code: MEG
Dated: January 20, 1999
Received: January 21, 1999

Dear Mr. Hogancamp

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:

Device Name: Science Incorporated PDS Personal Infusor with Drug Disposal Septal Port

Indications for Use:

The Science Incorporated PDS Personal Infusor with Drug Disposal Septal Port is designed for the ambulatory infusion of physician-prescribed parenteral medications. The device is intended to be filled and prepared for administration by pharmacists, and provided to patients who have been trained in the pump's operation. The device is, also, designed to allow for the removal of parenteral medication to allow for the proper disposal of both the device and the medication where disposal of both together would be contrary to normal professional health care practice.

The flexibility offered by the PDS Personal Infusor with Drug Disposal Septal Port will enable physicians to choose from a variety of fluid flow rates and drug concentrations. It will provide clinicians and patients with a convenient and efficient option for administration of fluid medications to patients, as well as allow for proper disposal of device and unused fluid medications.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Patricia Cucente

(Division Sign-Off)
Division of Dental, Infection Control,
and General Hospital Devices
510(k) Number K990208

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

(Optional Format 1-2-96)