

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 **Personal Infusor** is technologically similar to the **Baxter Intermate® SV** and the **Block Homepump Eclipse™**. However, it offers two improvements: 1) it features a single orifice rate control component that provides superior control of flow compared to the predicate devices, and 2) it has a flow indicator that displays the states of *Flowing*, *Blockage*, and *Empty*.

Performance data:

The **Science Incorporated Personal Infusor** exhibits improved flow performance when compared to the predicate devices. In our studies, the new devices displayed linearity of $\pm 10\%$ over a temperature range of 10-40° C when used with various diluents.



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

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

DEC - 4 1997

Re: K971362
Trade Name: Personal Infusor
Regulatory Class: II
Product Code: MEB
Dated: September 5, 1997
Received: September 5, 1997

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.

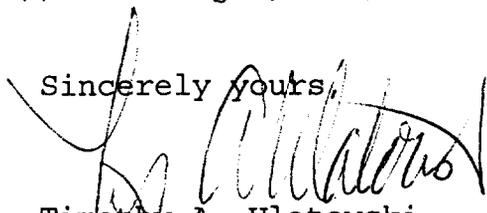
If your device is classified (see above) into either class II (Special Controls) or class III (Pre-market Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the current Good Manufacturing Practice requirement, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic (QS) 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) 594-4618. 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" (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: K971362

Device Name: Science Incorporated Personal Infusor

Indications for Use:

The Science Incorporated Personal Infusor 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 flexibility offered by the Personal Infusor will enable physicians to choose from a variety of fluid flow rates and drug concentrations, and will provide clinicians and patients with a convenient and efficient option for administration of fluid medications to patients.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Patricia Cuceniti

(Division Sign-Off)
Division of Dental, Infection Control,
and General Hospital Devices

510(k) Number K971562

Prescription Use ✓
(Per 21 CFR 801.109)

OR Over-The Counter Use _____

(Optional Format 1-2-96)