K970678

Appendix E Summary of Safety and Efficacy

JAN - 9 1998

Harvard Medical Inc.
22 Pleasant Street
South Natick MA 01760
(508)-655-2000

Contact Person: Eric J. Flachbart, Vice President, Research and Development
Date Prepared: 6 February, 1997

Trade Name: Harvard Library
Common Name: Computer Program
Classification Name: Infusion Pump

Predicate Devices

Shasta Logic - Clinicalc
A Mixed Bag Corp - Infusion Calculator
Harvard Apparatus - Harvard 2 Syringe Pump

Intended Use

The Harvard Library is intended to provide a vehicle to create and download a library of drug names and parameters to the Harvard 2 Syringe Pump. It is designed to lessen the likelihood of operator errors when entering drug information into the Harvard 2 Syringe Pump.

Technological Characteristics

The Harvard Library is a computer program which runs on MSDOS based personal computers under Microsoft Windows V3.1 or higher.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Mr. Eric J. Flachbart
Vice President, Research and Development
Harvard Apparatus Incorporated
22 Pleasant Street
South Natick, Massachusetts 01760

JAN - 9 1998

Re: K970678
Trade Name: The Harvard Library
Regulatory Class: II
Product Code: MRZ
Dated: October 14, 1997
Received: October 14, 1997

Dear Mr. Flachbart:

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 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

Indications For Use Statement

510(k) Number if known): K970678 TO BE ASSIGNED

Device Name: The Harvard Library

Indications For Use:

The Harvard Library is intended to provide a vehicle to create and download a library of drug names and parameters to the Harvard 2 Syringe Pump. It is designed to lessen the likelihood of operator errors when entering drug information into the Harvard 2 Syringe Pump.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Rebecca Cucente

(Division Sign-Off)
Division of Dental, Infection Control, and General Hospital Devices
510(k) Number K970678

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

(Optional Format 1-2-96)