

510(K) SUMMARY

Harvard Clinical Technology, Inc.
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Contact Person:

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Date Prepared: January 11, 2005

Trade Name: Harvard 2 Syringe Pump
Common Name: Syringe Infusion Pump
Classification Name: Infusion Pump

Predicate Devices
Harvard 1 Syringe Pump, Harvard 2 Syringe Pump

Intended Use

The Harvard 2 provides intravenous, intra-arterial, or epidural delivery of drugs or other parenteral fluids when administered by health care professionals such as physicians and nurses.

Device Description:

The Harvard Pump is intended for the delivery of parenteral fluids. It accommodates syringe sizes from 1 through 60 ml from multiple manufacturers.

Its user interface consists of an active matrix color LCD display with two rotary knobs for controlling pump operation. The rotary Data Entry knob provides scrolling and selection of data and menu items as well as state selection. The knob is turned to scroll, and pressed for selection. The rotary Function knob controls the state (Purge, Setup, Stop, Run and Bolus) of the pump.

The pump has several microprocessors, one master which controls operation of the device, one pump processor which controls the operation of the motor and sensors specific to the syringe drive mechanism, and one supervisor which monitors the status of the system.

The pump has sensors which permit its microprocessors to determine the syringe size loaded, determine if the syringe plunger is securely captured by the pusher block assembly, measure occlusion force and calculate the proper rate and distance the plunger of the syringe must travel to cause an infusion of fluid at a given rate and volume.

The pump provides for bidirectional remote communications via an RS232 serial port.

The pump may be used with The Harvard Library, an optional computer program which runs on MS Windows based personal computers. The Harvard Library is capable of downloading and uploading drug information in the form of a drug library to and from the pump. After downloading, the drug library is resident in flash memory within the pump, enabling the pump to provide drug specific defaults for drug concentrations, pumping rates, bolus amounts, and bolus times.

Barcode versions of the pump provide a laser scanning barcode reader. The barcode reader is used to scan a label placed on the syringe which selects a drug from the pump's resident drug library. This allows the pump to retrieve from its internal memory the drug's specific parameters such as concentration, infusion rate etc. in an effort to minimize user input errors.



FEB 11 2005

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

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

Re: K050107
Trade/Device Name: Harvard 2 Syringe Pump, Model 2001-001
Regulation Number: 880.5725
Regulation Name: Infusion Pump
Regulatory Class: II
Product Code: FRN
Dated: January 11, 2005
Received: January 19, 2005

Dear Mr. Flachbart:

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), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act 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/industry/support/index.html>.

Sincerely yours,



Chiu Lin, Ph.D.

Director

Division of Anesthesiology, General Hospital,

Infection Control and Dental Devices

Office of Device Evaluation

Center for Devices and

Radiological Health

Enclosure

Attachment 2 Indications for Use Statement

510(k) Number: K050107

Device Name: Harvard 2 Syringe Pump

Indications for Use:

The Harvard 2 provides intravenous, intra-arterial, or epidural delivery of drugs or other parenteral fluids when administered by health care professionals such as physicians and nurses.

Prescription Use ✓
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use _____
(21 CFR 801 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Anton V. ...
(Division Sign-Off)
Division of Anesthesiology, General Hospital,
Infection Control, Dental Devices

510(k) Number: K450107