K033054

DEC 16 2003

510(K) SUMMARY

Harvard Clinical Technology Inc.
22 Pleasant Street
South Natick MA 01760

Contact Person:

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Date Prepared: July 23, 2003

Trade Name: Harvard 1 Syringe Pump, Harvard 1 with PCA Pump
Common Name: Syringe Infusion Pump
Classification Name: Infusion Pump

Predicate Devices
Harvard 2 Syringe Pump, Medex Protégé, B. Braun Horizon with Dose Scan, Baxter PCA-II

Intended Use

Harvard 1

The Harvard 1 is designed to provide, intravenous, intra-arterial, or epidural delivery of drugs, blood or blood products or other parenteral fluids when administered by a health care professionals such as physicians and nurses.

The Harvard 1 is compatible for use inside the MRI room when mounted outside the 150 gauss line with MRI systems of 1.5 tesla or less.

Harvard 1 with PCA

Harvard with PCA to provide patient controlled analgesia, intravenous, intra-arterial, or epidural delivery of drugs, blood or blood products, or other parenteral fluids when administered by a health care professionals such as physicians and nurses.

The Harvard 1 with PCA is compatible for use inside the MRI room when mounted outside the 150 gauss line with MRI systems of 1.5 tesla or less.

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 controling 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 Harvard 1 with PCA extends the Harvard 1 functionality to include Patient Controled Analgesia capability through the addition of an optional PCA pendent and PCA cover and lock assembly. PCA capability allows the patient to request delivery of a dose of pain medication from a regimen prescribed by the physician.

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.

[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]
Warnings / Status	Purge Setup Stop Run Bolus AC Power Battery Charging Remote Syringe will be empty in 15 minutes Battery will be depleted in 30 minutes	Purge Setup Stop Run Bolus AC Power Battery Charging Remote Syringe will be empty in 15 minutes Battery will be depleted in 30 minutes	Purge Setup Stop Run Bolus AC Power Battery Charging Remote Syringe will be empty in 15 minutes Low Battery	Purge Stop	Infusion near end Infusion end Hi-pressure-Occlusion System Malfunction Syringe not capture Plunger disengaged Low Battery	Hold time exceeded Low battery Low flow from

Parameter	Harvard 1	Harvard with PCA	Harvard 2	Baxter PCA II	Protégé 3010	B. Braun Horizon Lite
Alarms	Occlusion Battery will be depleted in 5 minutes Syringe plunger not captured Syringe barrel Pusher moved Syringe Empty System Fault System Fault - Battery Depleted	Occlusion Battery will be depleted in 5 minutes Syringe plunger not captured 1 hour limit reached Syringe barrel Pusher moved Syringe Empty System Fault System Fault – Battery Depleted	Occlusion Battery will be depleted in 5 minutes Syringe plunger not captured Syringe barrel Pusher moved Syringe Empty System Fault System Fault – Battery Depleted	Occlusion Door open Door unlocked 1 hour limit reached Syringe plunger not captured Syringe empty Battery depleted System Fault	Infusion end Hi-pressure-Occlusion System Malfunction Syringe not capture Plunger disengaged Low Battery	Air-in-line Container empty Door open Downstream occlusion container System error Upstream occlusion Set improperly loaded
Inputs	Concentration Rate Bolus amount Bolus time Syringe manufacturer Syringe size[3] Patient weight Dose amount Dose time Number of doses Dose interval	Concentration Rate Bolus amount Bolus time Syringe manufacturer Syringe size Patient weight Dose amount Dose time Number of doses Dose interval PCA dose 1 hour limit	Concentration Rate Bolus amount Bolus time Syringe manufacturer Syringe size Patient weight Dose amount Dose time Number of doses Dose interval	Concentration Basal Rate Bolus Amount PCA Amount 1 Hour limit PCA Delay time Number of PCA does Dose interval	Concentration Rate Bolus amount Bolus time Syringe manufacturer Syringe size Patient weight Dose amount Dose time Number of doses Dose interval	Concentration Rate Bolus amount Bolus time Patient weight Dose amount Dose time Number of doses Dose interval
Serial Communications	Bidirectional	Bidirectional	Bidirectional	None	Bidirectional	Unknown
Barcode Reader	Optional laser scanning reader	Optional laser scanning reader	None	None	None	Laser scanning reader
MRI Compatibility	Yes	Yes	No	No	Yes	No

[3] Detected by syringe size mechanism and confirmed by user.

Summary of Performance Testing

Performance testing using prototype pumps which functionally reflect the final design configuration was performed to support the substantial equivalence claims.

Performance Test	Results Summary
Gravimetric Rate Accuracy and occlusion system testing per IEC-601-2-24 - Particular requirements for safety of infusion pumps and controllers.	Gravimetric Rate Accuracy test results indicate a mean error within the +/- 2% specification. Occlusion test results indicate a mean error within the specified range of the device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC 16 2003

Harvard Clinical Technology
Ms. Susan Gill
Responsible Third Party Official
Underwriters Laboratories, Incorporated
12 Laboratory Drive
Research Triangle Park, North Carolina

Re: K033054
Trade/Device Name: Harvard 1 Syringe Pump/ Harvard 1 with PCA Syringe Pump
Regulation Number: 880.5725
Regulation Name: Infusion Pump
Regulatory Class: II
Product Code: MEA, FRN
Dated: December 1, 2003
Received: December 2, 2003

Dear Ms. Gill:

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 (301) 594-4618. 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/dsma/dsmamain.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

INDICATIONS FOR USE

Harvard Clinical Technology, Inc

510(k) Number (if known): K033054
Device Name: Harvard 1
Harvard 1 with PCA
Syringe Pumps

Indications For Use:

Harvard 1

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

510(k) Number: K033054

Prescription Use ✓ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

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