K110578

MAR COR PURIFICATION
A Cantel Medical Company

MAY 2 0 2011

Millenium HX
Portable Reverse Osmosis Water Purification System

510(k) Summary of Safety and Effectiveness

Manufacturer: Mar Cor Purification, A Cantel Medical Company

Address: 14550 28th Avenue North
Minneapolis, MN 55447 USA
(800) 633-3080

Official Contact: Brent Geiger, MS, RAC
Senior RA Specialist

Trade Name: **Millenium HX**
Common Name: Water Purification System
Classification Name: Subsystem, water purification
Product Code: FIP
Device Class: II
Classification Reg: 876.5665

Mar Cor Purification has supplied the following information to the US Food and Drug Administration to support substantial equivalence of the Millenium HX Portable Reverse Osmosis (RO) Water Purification System to other portable RO water purification systems currently cleared for sale in the U.S.

1. Device Description

The device is a portable water purification system that uses reverse osmosis to remove contaminants from water that is used to dilute dialysis concentrate to form dialysate for use in hemodialysis equipment. Feed water enters the unit and is directed through a pump into a RO membrane. The pump applies a high hydrostatic pressure that forces water from the concentrated (feed) side to the dilute (product) side of the RO membrane. As water flow across the membrane all types of water contaminants except dissolved gasses are removed and the purified product water is then supplied to hemodialysis equipment.

The Millenium HX is capable of generating purified water that meets AAMI water quality requirements for hemodialysis at a minimum of 0.26 US gallons/minute (1.0 liters/min). It must be used with appropriate pre and post treatment units, including at a minimum carbon adsorption media pretreatment in order to remove chlorine/chloramines. Additional pre and post treatment requirements may vary and are dependent on the quality of the local feed water supply and individual facility requirements.

The Millenium HX system is designed to maintain low microbiological levels in the flow pathway through regular heat disinfection and chemical sanitization. Notable components and features of the Millenium HX include:

- RO membrane
- System pump
- Water quality monitoring system
- Operating panel and programmable logic controller (OPLC)
- Heat disinfection and chemical sanitization capability
- Audible and visual alarms
- Automatic divert to drain mode upon start-up and anytime product water TDS is above the quality set-point
- System control via a touch-screen user interface

2. Intended Use

The Mar Cor Purification Millenium HX Portable Reverse Osmosis Water Purification System is intended to be used as a dialysis accessory to produce water through reverse osmosis for use with hemodialysis equipment.

The Millenium HX can be connected to hemodialysis equipment used in hospitals, clinics and in home environments, in conjunction with the appropriate pre and post treatment units, as a part of a water treatment system designed to meet current AAMI and Federal (U.S) standards.

3. Comparison to Other Devices in Commercial Distribution Within the United States

The Millenium HX is equivalent in function and indications to the Mar Cor (formerly Gambro) WRO 300H (K093608), the Mar Cor Semper Pure RO system (K003877) and the Mar Cor Millenium Portable RO System 750 (K964539). All of the products are portable reverse osmosis water purification systems with the same intended use and equivalent indications for use. Both the Millenium HX and the WRO 300H share the same capability for system heat disinfection.

4. Summary of Non-Clinical Performance Data

Mar Cor Purification has provided testing to show that the Millenium HX is safe and effective for its intended use based on the requirements listed in FDA's Guidance for the Content of Premarket Notifications for Water Purification Components and Systems for Hemodialysis (May 1997) and the FDA recognized consensus standard ANSI/AAMI RD62:2006 Water Treatment Equipment for Hemodialysis Applications. The following types of data were provided to FDA to support substantial equivalence to predicate devices and to demonstrate that the Millenium HX performs as intended.

- System and RO Membrane Performance – Flow and product water quality verification over range of operating conditions
- Heat Disinfection Process Validation
- Chemical Sanitization Validation
- Material Compatibility and Biocompatibility

- Chemical Sanitization and Cleaning Rinsing Verification
- Software Validation
- Electrical Safety and Electromagnetic Compatibility
- Risk Analysis

5. Conclusion

Mar Cor Purification has provided appropriate premarket notification information in the form of a 510(k) to support the substantial equivalence of the Millenium HX to legally marketed predicate devices. The information and performance data provided indicates that the Millenium HX is safe and effective for its intended use when used in accordance with the device labeling.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
10903 New Hampshire Avenue
Document Mail Center - WO66-G609
Silver Spring, MD 20993-0002

MAR COR® Purification, Inc.
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MAY 20 2011

Re: K110578
Trade/Device Name: Millenium HX
Regulation Number: 21 CFR §876.5665
Regulation Name: Water purification system for hemodialysis
Regulatory Class: II
Product Code: FIP
Dated: February 28, 2011
Received: March 2, 2011

Dear Mr. Geiger:

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. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to 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); medical device reporting (reporting of medical device-related

adverse events) (21 CFR 803); 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.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

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) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Herbert P. Lerner, M.D., Director (Acting)
Division of Reproductive, Gastro-Renal
and Urological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) number (if known): K110578

Device Name: **Millenium HX**

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Prescription Use __X___ (Part 21 CFR 801 Subpart D) AND/OR Over-the-Counter Use_____ (Part 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)

(Division Sign-Off)
Division of Reproductive, Gastro-Renal, and Urological Devices
510(k) Number K110578