OCT 20 2004

510(k) Summary

This 510(k) Summary is provided as part of the Premarket Notification to comply with the provisions of the safe Medical Devices Act of 1990 requiring that either a summary be included in a submission or a statement that a summary is available upon request.

Submitter

Robert A Oliver
Mega Services
11730 Lost Meadows
Cibolo, TX. 78108
210-945-8448
210-861-2549
12-30-2003

Device Name

Mega Pure Cart or MPC1

Common or usual name

Deionization system with pre and post treatment for Acute dialysis.

Classification name

Water purification system for hemodialysis (21CFR 876.5665)

Device Description

The Mega Pure Cart (MPC1), is intended for use with a hemodialysis system to remove organic and inorganic substances and microbial contaminants from water used to dilute dialysate concentrate to form dialysate, and to produce purified water for other purposes such as dialyzer reprocessing and equipment rinse and disinfection. The MPC is a portable unit and is designed for single patient use only within a Hospital or Clinic setting.

The Mega Pure Cart purifies potable feed water through deionization. Deionization is used to remove 99.99+% of ions from water. Deionization alone does not remove particulates, organics, bacteria, viruses or endotoxins. The system is designed for hemodialysis application to treat carbon filtered potable water. Inappropriate use can result in the formation of Nitrosamines in the effluent of the deionizer.The purpose of the pretreatment section of the system is to condition the feed water supplying the deionizers. Conditioning the feed water will include: check valves to prevent backflow into the potable water source, one carbon tank and one carbon cartridge equipped with a test port between them to test for water conductivity, pH and chlorine/chloramines residual. This carbon is granular activated carbon with 12 x 40 mesh size and a iodine number of greater than 900. The purpose of the post treatment is to remove bacteria and endotoxins or lower them to within acceptable limits allowed by AAMI standards. The post treatment section of the system will include: sub micron/ ultra filter after the deionizer.

The alarm system will consist of two temperature compensated audible/visual alarms. The first alarm located after DI cartridge #1 and #2 is a 1meg ohm alarm and the second alarm is a temperature compensated audible/visual alarm and is pre set a 1 Meg ohm for final water quality. Routine monitoring of the test port #1 is necessary to detect any chlorine/chloramines breakthrough. Should any of the alarms sound during the treatment, the treatment should ***stop immediately*** and follow the DI cartridge exchange procedure listed in the operator's manual.

Based on a feed water quality of 266 ppm of TDS and 16 gpg of water hardness. Mega Pure Cart will produce typically 175 gallons of purified water that meets requirements of the standard issued by the American National Standard Institute and the Association for the Advancement of Medical Instrumentation: ANSI/AAMI RD 62:2001, Water Treatment For Hemodialysis Applications. There was also a test ran with the city water quality of 6 gpg of water hardness and a TDS of 197 ppm, and there was 225 gallons of purified water produced.

Predicate Device k022747

The Mega Pure Cart and pretreatment and water purification are substantially equivalent to HydroPure system for dialysis, which utilize carbon and deionization cylinders to purify water for hemodialysis.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 2 0 2004

Mr. Robert Oliver
Mega Services
106 Lost Meadows Drive
CIBOLO, TX 78108

Re: K031832
Trade/Device Name: Mega Pure Cart Portable Water Purification System (Model MPC1)
Regulation Number: 21 CFR §876.5665
Regulation Name: Water purification system for hemodialysis
Regulatory Class: II
Product Code: 78 FIP
Dated: September 13, 2004
Received: September 17, 2004

Dear Mr. Oliver:

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 (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 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 one of the following numbers, based on the regulation number at the top of this letter:

21 CFR 876.xxxx	(Gastroenterology/Renal/Urology)	240-276-0115
21 CFR 884.xxxx	(Obstetrics/Gynecology)	240-276-0115
21 CFR 892.xxxx	(Radiology)	240-276-0120
Other		240-276-0100

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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,

Nancy C. Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

510(k) K031832

Company Name: Mega Services

Device Name: Mega Pure Cart

Model Number: MPC1

Indications For Use:

The Mega Pure Cart (MPC1), is intended for use with a hemodialysis system to remove organic and inorganic substances and microbial contaminants from water used to dilute dialysate concentrate to form dialysate, and to produce purified water for other purposes such as dialyzer reprocessing and equipment rinse and disinfection. The MPC is A portable unit and is designed for single patient use only within a Hospital or Clinic setting.

Concurrence of CDRH, Office of Device Evaluation (ODE)

Nancy C Brogdon

(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K031832

Prescription Use ✓
(Per 21 CFR 801.109)