K030652
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510(k) Summary

1. **Submitter's Information**
   USFilter/Ionpure Inc.
   10 Technology Dr.
   Lowell, MA 01851
   p) 978-614-7359
   f) 978-441-6037
   Robert Dudek, Regulatory Compliance Manager
   February 27, 2003

2. **Device Information**
   Name: MedRO™-SPD
   Common Name: Single Patient Dialysis Reverse Osmosis Unit
   Classification: Water Purification Component for Hemodialysis

3. **Predicate Device Information**
   MedRO™ Reverse Osmosis System
   (# K013677)

4. **Device Description**
   MedRO™-SPD is a reverse osmosis unit used to purify water in hemodialysis applications.

5. **Intended Use**
   The MedRO™-SPD is intended to be used as a component of a water purification system for Hemodialysis.

6. **Comparison to Predicate Device**
   The MedRO-SPD™ and the MedRO™ both provide the same function using the same technology. The fundamental difference is the MedRO-SPD™ is smaller in size to the MedRO™. Both systems are designed to remove contaminants from the water supply prior to use in hemodialysis treatment by using the method of Reverse Osmosis. Both units utilize RO membranes in a single pass multi-stage format; feed water is passed through a series of 3 membranes to purify the water. Both systems measure quality of water and pressure and provide alarms when preset requirements aren't met. Both systems are also designed so the product water will meet AAMI RD5 quality water.

7. **Non-clinical Performance Data**
There were three hardware validations performed and product water samples drawn to test for AAMI water quality, bacteria, and endotoxin from the MedRO™-SPD unit.

The Installation Qualification (IQ) was performed to verify the components used to construct the MedRO™ unit were installed according to design specifications and drawings. The system was installed in accordance with the P&ID, Electrical Schematic, Bill of Material, and Operations & Maintenance Manual. There were two discrepancies noted and corrected. The first discrepancy was found on the electrical drawing, RX101-051, the transformer was not drawn correctly. The drawing has been revised and is now correct. The second discrepancy was found in the P&ID, RX101-003. The drawing indicated Polyethylene tubing which is not appropriate for medical use, the drawing has since been corrected to indicate polypropylene tubing. The tubing and vessels passed the hydrostatic testing that was performed. The unit was designed, assembled and installed with no deadlegs. The alarms were given forced conditions from the O&M Manual and were operational. The MedRO™-SPD unit passed the Installation Qualification.

The unit ran for 14 hours while performing the Operational Qualification (OQ). This was performed to provide evidence that the unit will operate according to design specifications. The unit was tested for proper response in the case of a power failure. Concluding that it will shut off during a power failure and require a manual re-start upon the power being restored. The unit was ran through all operating sequences that are specified in the O&M Manual and verified the output of the device responded and that those responses were correct. Switches, buttons and indicators were tested to verify the functions and displays are what were specified. Alarm conditions were simulated to verify that the unit would alarm for necessary conditions.

A Failure Analysis Test (FAT) was performed to ensure that when the system is introduced to failures that it operates as specified. The reject value was set to 100% (100% rejection is an unachievable limit which will force the system into alarm simulating a low quality reading) and the Low Quality Alarm did sound. The water pressure was set below the 15-psi requirement; the unit shut down and required manual re-start to restore power to the unit. The system was also tested to indicate accurate rejection, feed water quality, product water quality and current set points. The unit passed the Failure Analysis Test.

In addition to the above testing, water samples were collected to test the unit for AAMI quality water; bacteria and endotoxin requirements set by AAMI. At this time the FDA does not recognize the AAMI limit for endotoxin, but because the end user will test for endotoxin levels we felt it would be informative to provide this test also. The unit was installed to a potable water source with a 10" carbon filter preceding the unit (to protect the membranes from chlorine) and ran for 30 minutes prior to sampling. The unit was able to significantly reduce the chemical contaminants in water to amounts below the FDA recognized standard. The unit was also able to reduce bacteria and endotoxin in the product water.

8. **Clinical Performance Data**
   This unit is not required to have Clinical Test performed.

9. **Conclusions of Performance Data**
   The MedRO-SPD unit passed a battery of diagnostic tests including, three hardware validations, AAMI water analysis, bacteria and endotoxin testing. Two samples were drawn for the water testing to assure reproducibility of these results.

10. **Additional Safety & Effectiveness**
    In addition to the testing conducted for this submittal, the USFilter service/installation facility follows procedure 11.030, Service Department Responsibility for Dialysis Installation and Start-up, in our QSR Manual (see #K980182). According to this procedure the unit must pass acceptable bacteria, endotoxin and chemical contaminant criteria prior to releasing the unit to the end user.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP - 3 2003

Mr. Robert Dudek
Regulatory Compliance Manager
U.S. Filter/Ionpure, Inc.
10 Technology Drive
LOWELL MA 01851

Re: K030652
Trade/Device Name: Med-RO™-SPD (Single Patient Dialysis Reverse Osmosis)
Regulation Number: 21 CFR §876.5665
Regulation Name: Water purification system for hemodialysis
Regulatory Class: II
Product Code: 78 FIP
Dated: June 4, 2003
Received: June 5, 2003

Dear Mr. Dudek:

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 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 the letter:

8xx.1xxx	(301) 594-4591
876.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4616
884.2xxx, 3xxx, 4xxx, 5xxx, 6xxx	(301) 594-4616
892.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4654
Other	(301) 594-4692

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" (21CFR Part 807.97) you may obtain. Other general information on your responsibilities under the Act may be obtained 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

Indications for Use

The USFilter MedRO - SPD is a single/acute care patient reverse osmosis unit intended to supply water that is used for hemodialysis treatments. The water produced will meet the minimum water quality requirements as specified by ANSI/AAMI American National Standard for Water Treatment Equipment for Hemodialysis Applications (RD5:1992 and RD62:2001) and the CSA Water Treatment Equipment and Water Quality Requirements for Hemodialysis (CSA-Z364.2.2-03) when used as directed. Dependent on feed water quality this unit may be used in conjunction with other approved water treatment components.

Nancy C Brogdon

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices

510(k) Number K030652

Prescription Use ✓
(Per 21 CFR 801.109)