MAR 8 2002

510(k) SUMMARY

This summary of 510(k) safety and effectiveness information is being submitted by USFilter/Ionpure, Inc. in accordance with the requirements of 21 CFR§807.92.

The assigned 510(k) number is:

1 **Original Submitter's Name:**
USFilter/Continental Water Systems

2 **Submitter's Identification**
USFilter/Ionpure, Inc.
725 Wooten Road
Colorado Springs, CO 80915
719-570-9600

Date Summary Prepared
15 October 2001

3 **Official Correspondent/Contact**
David A. Dentino
10 Technology Drive
Lowell, MA 01851
978-614-7359

4 **Name of the Device**
Med-RO™ Reverse Osmosis System

5 **Predicated Device Information**
USFilter/Ionpure, Inc. M-Series Reverse Osmosis Water Purification System

6 **Device Description**
The Med-RO™ Reverse Osmosis System is a machine used to purify water.

7 **Intended Use**
The Med-RO™ Reverse Osmosis System series is intended to be used as a component of a water purification system for Hemodialysis.

8 **Comparison to Predicated Devices**
The Med-RO™ Reverse Osmosis System unit contains the same fundamental scientific technology as the predicated device. Device modification, that will not negatively affect performance, safety, or effectiveness are detailed in Exhibit A section 1.

9 **Discussion of Non-Clinical Test Performed for Determination of Substantial Equivalence is as follows:**
Based on the testing performed as well as the information provided, there are no changes in the performance, safety or effectiveness of the modified device.

10 **Discussion of Clinical Test Performed:**
N/A

11 **Conclusions:**
As was true for the original USFilter/Ionpure, Inc. M-Series Reverse Osmosis Water Purification Systems, the intended use of the Med-RO™ Reverse Osmosis system is intended to purify water for Hemodialysis when used as a component of a complete water purification system.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 8 2002

U.S. Filter/Ionpure, Inc.
C/o Mr. David A. Dentino
Regulatory Compliance Manager
USFilter/S&P
10 Technology Drive
LOWELL MA 01851

Re: K013677
Trade/Device Name: Med-RO™ Reverse Osmosis System (Modified)
Regulation Number: 21 CFR §876.5665
Regulation Name: Water purification system for hemodialysis
Regulatory Class: II
Product Code: 78 FIP
Dated: February 5, 2002
Received: February 6, 2002

Dear Mr. Dentino:

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 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:

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" (21 CFR Part 807.97). 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

510(k) Number (if known): K013677

Device Name: Med-RO™ Reverse Osmosis System

Indications For Use:

The USFilter/Ionpure Med-RO™ Reverse Osmosis System is intended to supply water for use in the preparation of dialysate for hemodialysis patients and for other hemodialysis-related procedures such as cleaning, rinsing of equipment, and reprocessing of dialyzers. 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 RD 62:2001[RD-5: 1992 if applicable]. The Med-RO™ Reverse Osmosis System is intended to be used in conjunction with other components of a water treatment system as necessary with compatible input and output water requirements.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Nancy C Brogdon

(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K013677

Prescription Use ✓
(Per 21 CFR 801.109)