JAN 24 2000

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510 (K) SUMMARY

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

The assigned 510(k) number is K993200.

1) Submitter's Identification:
Isopure Corporation
11700 Commonwealth Drive
Suite 605
Louisville, Kentucky 40299

Date Summary Prepared:
September 20, 1999

2) Name of The Device:
MD 420/440/460/470/480/490 Multi- Patient Reverse Osmosis (RO) Machine.

3) Predicate Device Information:
Multi-Patient Reverse Osmosis (RO) Water Treatment System MD 400 Series.

4) Device Description:
The MD 420—490 Series is a Reverse Osmosis Machine used in purifying water.

5) Intended Use:
The MD 420—490 Series is intended to purify water for Hemodialysis when used as a component of a complete water purification system.

6) Comparison to Predicated Device:
The MD 420—490 series features an advanced electronic package including a PLC with software and validation procedures and a Touch-screen. The new advanced system has the capability to monitor both the pre-treatment and post-treatment of the water room. The data can be printed for a daily log or modem to a remote location.

7) Discussion of Non-Clinical Test Performed for Determination of Substantial Equivalence are as follows:
Based on the information submitted, there are no changes in the safety of effective issues.

8) Discussion of Clinical Test Performed:
N/A

9) Conclusions:
As was true for the original registered HD400A—F Reverse Osmosis (RO) machine device, the intended use of the modified RO machine device, i.e. the MD 420—490 series, is intended to purify water for Hemodialysis when used as a component of a complete water purification system.

EXHIBIT A:

SECTION 1: DEVICE MODIFICATION DESCRIPTION

1.1 Intended Use: As was true for the original registered HD40OA--F Reverse Osmosis (RO) Machine device (510(k) application #K944385), the intended use of the modified RO machine device, i.e., the MD420-490 series, is intended to purify water for Hemodialysis when used as a component of a complete water purification system. The device name change from MD 400 A—F to MD 420--490 was to facilitate recognition of a medical device (MD) 400 series as multi-patent and 20-90 as the total machine membranes 420 (2 membranes) 440 (4 membranes) etc. The text of the original 510(k), though of limited explicit information characteristic of its time of submission, is included for reference (**See Exhibit E: Section 10**).

1.2 Rationale: The rationale for modifying the original registered device is straightforward. First, the original design, although very useful at the time, now proves to be very nosey and cluttered with pipes, valves, etc. This made the machine very hard to operate and maintenance proved very costly. Second, the horizontal position of the Goulds pump resulted in complete pump failures costing IPS large sums of money in pump failures resulting in the sale of the company in 1998 to Isopure Corp. Third, with the FDA now requiring a complete registration of the entire water system, this machine with the use of a PLC, will record data for all aspects of the water system tying the pre-treatment and storage tank back to the RO for one central location for all of the data. This information is also modemable to a remote location. Fourth, the machine is now simpler, quieter, and easier to maintain, run, and service compared to the MD 400 A—F.

1.3 Background: It was, and remains, the opinion of the applicant that the change from a mechanical device entrained changes attendant to a automated device, were subject to documentation for the models of the original registered device series (MD400A-F, now MD 420--490). The PLC change and entrained changes are listed later in this exhibit (**See Exhibit A: Section 1.9, "Table of Differences"**). Marketing of these devices continues. In addition, long before changing to the new PLC, MD 40OD--E models were constructed and sold using the same original circuitry to meet the growing purified water volume demands of the dialysis market. The MD400 D--E devices, now the MD 420-490 also underwent alteration and are equipped with PLC circuitry. Again, it was felt that the PLC could offer a much broader control of the entire system per the FDA requirements. The original conductivity control a Myron L conductivity controller used to monitor the conductivity of the water and also control the "Diversion to Drain" of the machine remains the same as on the original registration. The PLC can monitor all aspects of the water room including the RO, pre-treatment, storage tank, line and loop pressures, temperatures, and flows. The system will display membrane % rejection and % recovery. All of this data is sent back to the PLC on the RO where it is displayed. The data also has the capability to be modemed to a remote location. Isopure would also like to offer a "Remote Monitoring Service" where we would call up the machine from our location, review the data of the water room and fax or e-mail the results back to the clinic for their reports. The hydraulic design of the machine remains unchanged for the original 510(k) application, however, we now use SCH 80 PVC pipe and 316L Stainless Steel piping in place of the tubing originally used of the HD- MD series.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN 24 2000

Mr. Kevin Gillespie
President and CEO
Isopure Corporation
11700 Commonwealth Drive
Louisville, KY 40299

Re: K993200
MD 420/440/460/470/480/490 Reverse Osmosis Machine
Dated: October 24, 1999
Received: October 28, 1999
Regulatory Class: II
21 CFR §876.5665/Procode: 78 FIP

Dear Mr. Gillespie:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we 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). 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 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

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 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4613. 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 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers 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,

CAPT Daniel G. Schultz, M.D.
Acting Director, Division of Reproductive,
Abdominal, Ear, Nose and Throat,
and Radiological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K993200

Device Name: MD 420/440/460/470/480/490 Multi-patient Reverse Osmosis (RO) Machine

Indications For Use:

The MD 420-490 series reverse osmosis system is intended to purify water for hemodialysis when used as a component of a complete water purification system.

(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, Abdominal, ENT,
and Radiological Devices
510(k) Number K993200

Prescription Use ✓ OR Over-The-Counter Use ___
(Per 21 CFR 801.109)

(Optional Format 1-2-96)