



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 7 - 2004

Mr. Kevin Gillespie
Isopure Corporation
129 Citizens Blvd.
SIMPSONVILLE KY 40067

Re: K041163

Trade/Device Name: Isopure Complete Water System for Hemodialysis for Direct Feed
Single or Multi-Patient Hemodialysis Facilities, Indirect Feed utilizing
the MD610, MD620, MD630 and MD640 Ultra Filter System

Regulation Number: 21 CFR §876.5665

Regulation Name: Water purification system for hemodialysis

Regulatory Class: II

Product Code: 78 FIP

Dated: August 5, 2004

Received: August 9, 2004

Dear Mr. Gillespie:

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.

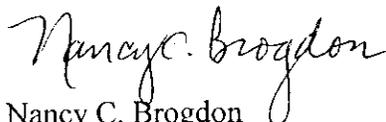
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to 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
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number: K041163

Device Name: Isopure Complete Water Purification System for direct feed Single or Multi-Patient Hemodialysis Facilities Indirect feed utilizing the MD610, MD620, MD630, MD640 Ultra Filter System.

Indications For Use:

The Isopure Complete Water Purification System each device is intended for use in Hemodialysis systems and is intended to remove organic and inorganic substances and microbial contaminants from water used to dilute dialysate concentrate to form dialysate. These systems are to be use in Hospitals and/or Hemodialysis facilities.

Each indirect feed model has the following optional configuration:

MD610 – Single distribution pump with a series of ultra-filters based on the required flow of the facility. The MD610 has no Deionization capabilities.

MD620 – Dual multi-stage distribution pumps with a series of ultra-filters based on the required flow of the facility. The MD620 has no Deionization capabilities.

MD630 – Single multi-stage distribution pump with a series of ultra-filters based on the required flow of the facility. The MD630 is equipped to process a single bank of medical grade Deionization exchange tanks.

MD640 – Dual multistage distribution pumps with automatic pump alternation with a series of ultra-filters based on the required flow of the facility. The MD640 is equipped to process dual banks of medical grade Deionization exchange tanks. The MD640 is capable of operating continuously by automatically alternating between the two banks of exchange tanks.

Prescription Use _____
(Per 21 CFR 801 Subpart D)

OR

Over-The-Counter Use _____
(21 CFR 807 Subpart C)

Concurrence of CDRH, Office of Device Evaluation (ODE)


(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K041163