OCT 21 2003

4. 510 (k) Summary of Safety and Effectiveness

This summary of 510(k) safety and effectiveness information is submitted in accordance with the requirements of the Safe Medical Device Act (SMDA) of 1990 and 21CFR 807.92

Applicant

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Prepared by

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Jerry Ponikvar, will respond to any requests for additional information.

Device Name

Trade Names
Biopure Portable RO System
Biopure 4400 Series RO System
Biopure 8400 Series RO System
Biopure Water Purification Pretreatment Components

Softeners	Biopure Performa Softener
	Biopure Magnum Series Water Softener
Backwash Filters	Biopure Performa Filter
	Biopure Magnum Series Carbon Filter
	Biopure Magnum Series Multimedia Filter
Service Deionization	Biopure Service DI
	Biopure Premium Grade Service DI
	BiopureCation Bed DI
	Biopure Anion Bed DI
	Biopure Auto DI
Organic Bed Service Carbon	
	Biopure Carbon

Biopure Product Water Distribution Components
Biopure CIP System
Biopure Hot Water Sanitization System

Common or Usual Names
Reverse Osmosis systems with pretreatment and product water distribution components

Classification Name
Water Purification System for Hemodialysis
Regulatory Classification – Class II
21 CFR 876.5665
Product Code: 78 FIP

Intended Use

The device is intended to remove organic and inorganic substances and microbial contaminants from water that is used to dilute dialysis concentrate to form dialysate, and to produce purified water for dialyzer reprocessing, and equipment rinse and disinfection.

Device Description

The Biopure Series RO systems purify feed water through reverse osmosis a membrane separation process. In reverse osmosis, pressure is applied to force water through a semipermeable membrane, while leaving impurities on the feed side of the membrane. The membrane allows the solvent (water) to pass through but retains a large percentage of impurities such as dissolved inorganics, organics, bacteria, and pyrogens. The water that passes through the membrane (permeate), has significantly less contamination than the feed water, while the reject stream, which remains upstream of the membrane, has a much higher concentration than the feed stream.

The purpose of a pretreatment to reverse osmosis is to remove chlorine/ chloramines and condition the feed water supplying the RO machine. The pretreatment section may include feed water boost pumps, a temperature blend valve, chemical feed unit, sediment/carbon cartridge filters, water softeners, multi media filters, carbon filters and dealkalizers.

The RO unit removes more than 99% of all micro-organisms, pyrogens, particles, and organics with a molecular weight greater than 300, and up to 95% of all dissolved inorganics. The elements of an RO unit include a prefilter, RO pressure pump, and RO membranes.

The purpose of a product water distribution system is to deliver water that meets or exceeds AAMI/ASAIO standards for water treatment equipment and water quality requirements for hemodialysis point of use. Additional product water treatment is intended to control or eliminate bacteria prior to point of use. The product water treatment system may include a storage tank, distribution pump, a distribution loop, UV disinfection, ultrafiltration, and hot water sanitization.

Depending on the series and model, Biopure water purification systems produce from 300 GPD (gallons per day) to 100 GPM (gallons per minute) at 75% recovery rate. Rejection of total dissolved solids and monovalent ions is in the range of 95%-99% depending on feed water characteristics. Colloids, bacteria, and organics larger than a 200 molecular weight are rejected at greater than 99%.

Biopure water purification systems produce product water that meets the requirements of ANSI / AAMI RD5-1992, Hemodialysis Systems.

Predicate Devices

The Biopure Series RO systems, pre-treatment components, and product water components are substantially equivalent to the following legally marketed devices:
Zyzatech Series RO systems, K964539
US Filter Water Purification System, K980182
These devices use reverse osmosis technology to purify water for hemodialysis applications.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 21 2003

Biolab Equipment Canada, Ltd.
c/o Mr. Jerry Ponikvar, P.Eng
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128 Grandview Avenue
Thornhill, Ontario
CANADA L3T 1H6

Re: K030348
Trade/Device Name: Biopure Portable RO System
Biopure 4400 Series RO System
Biopure 8400 Series RO System
Biopure Water Purification Pretreatment Components
Biopure Product Water Distribution Components
Regulation Number: 21 CFR §876.5665
Regulation Name: Water purification system for hemodialysis
Regulatory Class: II
Product Code: 78 FIP
Dated: July 22, 2003
Received: July 23, 2003

Dear Mr. Ponikvar:

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

3. Statement of Indications for Use

Applicant: Biolab Equipment Canada Limited

Establishment Registration # 9710313

510 (k) Number (if Known): K030348

Device Name:

Biopure Portable RO System
Biopure 4400 Series RO System
Biopure 8400 Series RO System
Biopure Water Purification Pretreatment System Components
Biopure Product Water System Components

Classification Name:

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Indications for Use:

The device is intended to remove organic and inorganic substances and microbial contaminants from water that is used to dilute dialysis concentrate to form dialysate and to produce purified water for dialyzer reprocessing, and equipment rinse and disinfection. Enclosed below is a chart indicating the physical differences of the different systems, areas of use, and patient population.

System Model	Biopure Portable	Biopure 4400	Biopure 8400
Area of Use	Home or hospital use, this systems allows dialysis treatment to patients not near a clinic	Hospital or Dialysis Clinics	Large Dialysis Clinics
Patient Population	1 to 3	3 to 50	65 to 600
Physical Dimensions	39" x 12.5" x 28"	72"x24"x32" to 72"x18"x144"	76"x32"x122" to 76"x44"x162"
Weight	120 to 135 lbs	220 to 1610 lbs	1200 - 8000 lbs

Prescription Use ✓
(Per 21 CFR 801.109)

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

510(k) Number K030348