OCT - 2 2003

1057

# 510(k) Summary

as required by section 807.92( c )

# *Aquaboss*® EcoRO Dia 50
# Portable Water Treatment for Hemodialysis

**Submitted by**
Lauer Ltd., Hong Kong
1301 Bank of America Tower
12 Harcourt Road
Hong Kong Central

**Manufacturer:** Lauer Membran Wassertechnik GmbH
Speichermatt 9 / 79599 Wittlingen (Germany)

**Contact:** Dr. Stephan Krietemeyer
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| | |
|---|---|
| **Date:** | 09/29/03 |
| **Classification Name:** | Water Purification System for Hemodialysis |
| **Common Name:** | Portable Water Treatment System |
| **Proprietary Name:** | ***Aquaboss***® EcoRO Dia 50 Portable Water Treatment System for Hemodialysis |

**Claiming substantial equivalence to:** Better Water Inc.
Water Treatment System for Hemodialysis
Medi-Port PB
(K954928)

K032004

K032004



## Classification panel:

## PART 876--GASTROENTEROLOGY-UROLOGY DEVICES

[Code of Federal Regulations]
[Title 21, Volume 8]
[Revised as of April 1, 2002]
From the U.S. Government Printing Office via GPO Access
[CITE: 21CFR876.5665]
[Page 363]
TITLE 21--FOOD AND DRUGS
CHAPTER I--FOOD AND DRUG ADMINISTRATION, DEPARTMENT OF HEALTH AND HUMAN SERVICES (CONTINUED)
PART 876--GASTROENTEROLOGY-UROLOGY DEVICES--Table of Contents
Subpart F--Therapeutic Devices
Sec. 876.5665 Water purification system for hemodialysis.

(a) Identification. A water purification system for hemodialysis is a device that is intended for use with a hemodialysis system and that is intended to remove organic and inorganic substances and microbial contaminants from water used to dilute dialysate concentrate to form dialysate. This generic type of device may include a water softener, sediment filter, carbon filter, and water distillation system.

(b) Classification. Class II (performance standards).

## Product Code:

FIP

## Regulation No.:

876 5665

## Directions for use:

The system produces water for diluting hemodialysis concentrates according to AAMI Standards RD5; RD62 (draft) and RD52 (draft). The system output rate is 50l/h. The temperature of the supplied water must not drop below 50°F (10°C). The system is designed and built for continuous operation. The selection of water treatment equipment for dialysis is the responsibility of the dialysis physician. Product water should be tested periodically according to the AAMI/CDV-3 RD62 standard.

## Device Description:

The ***Aquaboss***® **EcoRO Dia 50** Portable Water Treatment System is a complete water purification system and consists of a reverse osmosis (RO) and pre-treatment. It s designed to feed one Hemodialysis machine with water. In order to optimize the performance of the RO system, the following items for pre-treatment are utilized:

1) cartridge filters to remove suspended solids
2) activated carbon filtration to remove organics, namely chlorine and chloramines

To minimize bacterial growth in the permeate line, permeate is circulated dead space free from the membrane to the point of use (dialysis machine). Excess permeate is circulated into the raw water tank and is reprocessed.

***Aquaboss***® **EcoRO Dia 50** works on the reverse osmosis principle. Reverse Osmosis describes a process involving a pressure operated cross filtration system. The water flows under high pressure

tangentially to a semi permeable membrane. As it is the case with normal filtration the system is cleaned by allowing one component (water) of the mixture to be separated to pass through the membrane with almost no hindrance whereas the other components (dissolved and non-dissolved water contents) are held back to leave the filtration unit in the concentrate flow. This is a separation process in the molecular sector which does not change the components being separated either chemically, biologically or thermally.

In order to ensure that the microbiological quality of the permeate will be maintained, this system has:

- A dead space free stainless steel pressure vessel for the RO membrane.
- A hygienic design with smooth surfaces
- Automatic flushing program to remove impurities from the membrane surface (impulse backwashing)
- Automatic flushing during standby periods to exchange stagnant water
- Dead space free connection between Reverse osmosis and Dialysis machine

When requested by the facility physician, optional devices can include the following components

1) CART (four wheel transport unit for RO system and pretreatment) (Option)
2) water softener to remove scale-forming minerals (Option)
3) Wooden box to increase sound absorption (Option)

After pretreatment ((i.e. filter, water softener; charcoal filter, etc) the incoming raw water (**RW**) flows through the solenoid valve (**Y10**) into the break tank (**VL**). From there it is delivered by means of a pump **M1** to the membrane module **MM1**, by passing through the reverse osmosis membrane. The feed flow (raw water and circulation) is divided into the concentrate and permeate flow after the feed flow has passed through the membrane barrier.

Concentrate leaves the membrane module and passes through a needle valve (**NV**), which restricts the water volume flowing out, thus ensuring the production pressure. The concentrate flow regulated in this way is either circulated internally through the solenoid valve **Y2** back into the tank or is conducted to the drain outlet as waste water through solenoid valve **Y9**. The cycling of the system between **Y2** and **Y9**, and thus the regulation of the concentrate volume to be rejected is by means of time control.

Before beginning dialysis and during the reflushing periods the needle valve can be bypassed by opening the solenoid valve **Y6** so that the membrane can be cleaned with a higher volume for a defined period of time.

The permeate is conducted through a hose to the dialysis machine. From here it is fed by means of a coupling into the dialysis machine. Should the end user not call for the full amount of permeate, the unused water be returned to the break tank via a pressure holding valve which, in turn ensures constant ringline pressure. The following is measured in accordance with the process diagram: conductivity raw water (**CIS1**), Conductivity Concentrate (**CIS2**), Conductivity Permeate (**CIS3**) System pressure (**PIS1**),, temperature concentrate (**TIS**) and Temperature Permeate (**TS**).

***Performance Monitoring:***

The conductivity of the Permeate and the operating mode is continuously displayed on the LCD on the operators panel. Alarm and error messages are displayed on the LCD. All readings for conductivities (raw water, concentrate), system pressure, temperature are presented on the display on the operator's panel on request.

**Impulse backwash**

After the system has been switched on or after switchover from standby operation to dialysis operation the membrane and the complete system can be preflushed for 2 – 45 minutes. In this state the system carries out repeated backwashing operations and flushes concentrate down the drain.

**Cleaning & Disinfection:**

EcoRO Dia 50 has a menu-guided cleaning and disinfection program. By following the displayed messages a disinfection with peracetic acid disinfection products can easily be carried out by the operator.

**Standby operation**

If connected to raw water and drain, during standby EcoRO Dia 50 flushes automatically to reduce microbial growth in the system.

## Predicate Devices

The ***Aquaboss®* EcoRO Dia 50** Portable Water Treatment System is substantially equivalent to other water purification systems in commercial distribution in the United States to include the Better Water Inc. Water Treatment System for Hemodialysis (FDA Document Control Number K954928).

- Both systems utilize reverse osmosis for purification of water to be used for hemodialysis
- Both systems utilize a polyamide, thin film composite, spiral wound membrane for hemodialysis
- Both systems are intended to be used for water purification for hemodialysis.
- Both systems use substantially equivalent water contact materials for pumps, tubing and other fittings.
- Both systems can utilize chemical disinfection using peracetic acid disinfection products
- Both system display poor water quality and pressure alarms on a display
- Both systems monitor water quality on digitally displays

We therefore consider the ***Aquaboss®* EcoRO Dia 50** Portable Water Treatment to be substantially equivalent to the Better Water Inc. Water Treatment System for Hemodialysis (FDA document Control Number K954928). The following table provides the necessary information on the predicate device to which this system is substantially equivalent:

K032004



**Predicate Device**

| | |
|---|---|
| **Device Names** | Better Water Inc. Water Treatment System for Hemodialysis **Mediport PB** |
| **Intended Use** | Water Purification for Hemodialysis |
| **510(k) Number** | K954928 |
| **Approval Date** | 1996 |

## Intended use:

***Aquaboss*® EcoRO Dia 50** Portable Water Treatment System is intended for use in hemodialysis treatment. It is intended to remove organic and inorganic substances and microbiological contaminants from water used to dilute dialysate concentrate to form dialysate.

This indication statement is essentially the same as the indication statement for the predicate device.

## Technological Characters

Comparing the proposed device to the predicate device, some similarities and differences are noted in the design employed to accomplish the same intended use: Both systems utilize reverse osmosis for purification of water to be used for hemodialysis. Both systems utilize a polyamide, thin film composite, spiral wound membrane for hemodialysis. Both systems are intended to be used for water purification for hemodialysis. Both systems use substantially equivalent water contact materials for pumps, tubing and other fittings. Both systems can utilize chemical disinfection using peracetic acid disinfection products. Both systems display poor water quality and pressure alarms on a display. Both systems monitor water quality on digitally displays. The ***Aquaboss*® EcoRO Dia 50** Portable Water Treatment System for Hemodialysis has the additional advantage of having a dead space free connection of the permeate tubing with the dialysis and a raw water break tank. In addition gives the display detailed information about the systems settings and actual readings.

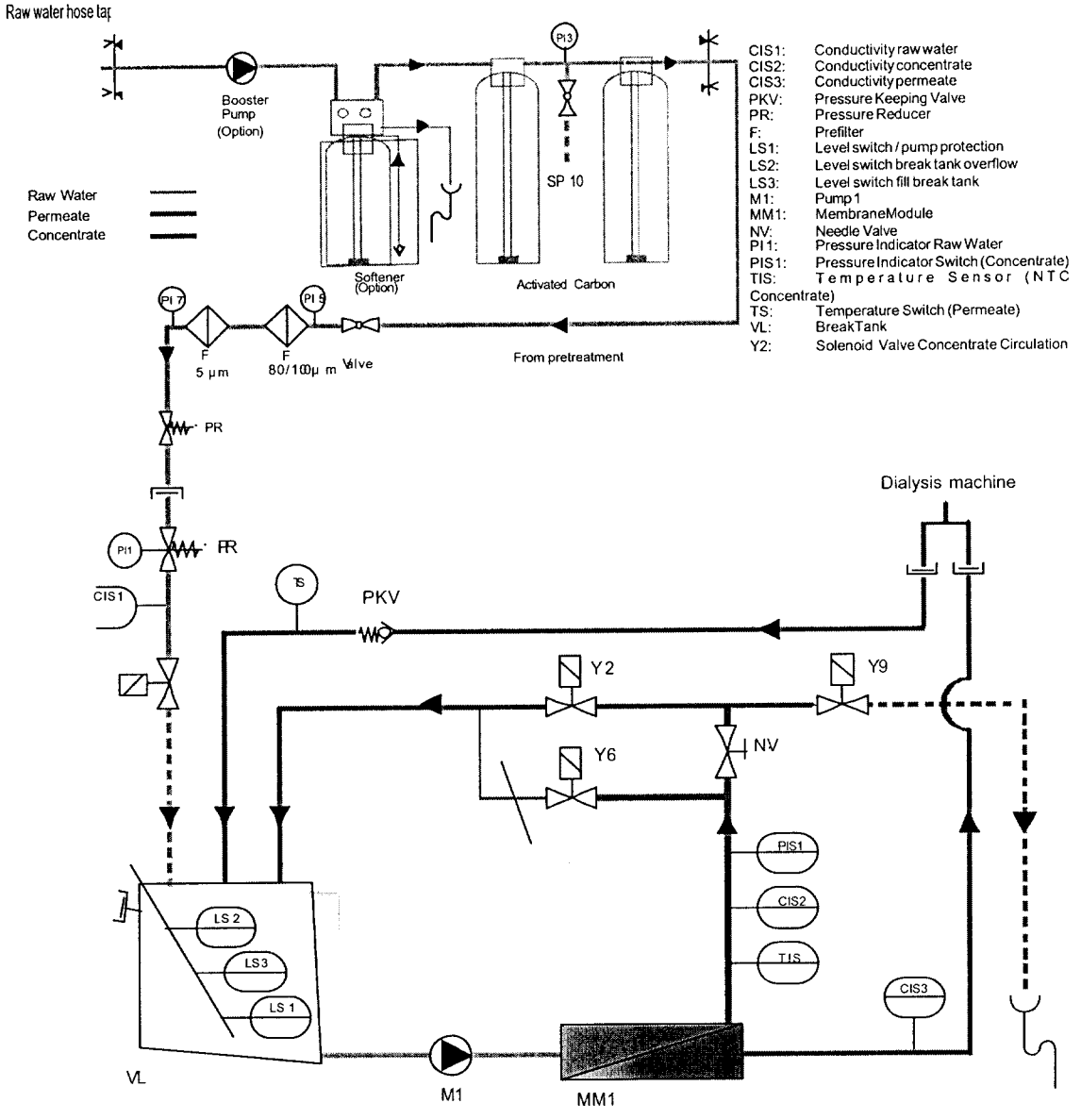
Wittlingen, Sept. 29th, 2003

Dr. S. Krietemeyer
Vice president
Manager engineering

K032004



## Appendix I: Pretreatment and EcoRO Dia 50 P&I Diagram



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT - 2 2003

Lauer Ltd., Hong Kong
c/o Mr. Stefan Preiss
TÜV America, Inc.
TÜV Product Service
1775 Old Highway 8
NEW BRIGHTON MN 55112

Re: K032004
Trade/Device Name: Aquaboss® EcoRO Dia 50 Portable Water Purification Systems for Hemodialysis
Regulation Number: 21 CFR §876.5665
Regulation Name: Water purification system for hemodialysis
Regulatory Class: II
Product Code: 78 FIP
Dated: September 1, 2003
Received: September 4, 2003

Dear Mr. Preiss:

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

1028

Attachment 1b



510(k) Number (if known): K032004

Device Name: ***Aquaboss***® EcoRO Dia 50 Portable Water Treatment System for Hemodialysis

Indications For Use:

***Aquaboss***® EcoRO Dia 50 Portable Water Treatment System for Hemodialysis.

***Aquaboss***® EcoRO Dia 50 Portable Water Treatment System for Hemodialysis is a device that is intended for use with a hemodialysis system. It is intended to remove organic and inorganic substances and microbial contaminants from water used to dilute dialysate concentrate to form dialysate.

The device includes carbon filter and sediment filter.
The device may include a water softener

***Aquaboss***® EcoRO Dia 50 Portable Water Treatment System for Hemodialysis is designed for the use in hospital or in home settings.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓
(P 21 CFR 801.109)

Over-The-Counter Use _____

(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K032004

(Optional Format 1-2-96)