

MAR 25 2013

510(k) Summary

As required by section 807.92(c)

Aquaboss® EcoRO Dia I + II (HT) Series Water Treatment System for Hemodialysis

Manufacturer: Lauer Membran Wassertechnik GmbH
Speichermatt 9 / 79599 Wittlingen (Germany)
Organization Number: 187230

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Date: 12/12/2012
Classification Name: Water Purification System for Hemodialysis
Common Name: Reverse Osmosis systems with pretreatment and product water distribution components
Proprietary Name: **Aquaboss®** EcoRO Dia I+II (HT) Series Water Purification System for Hemodialysis

Claiming substantial equivalence to:

Gambro Central Water Treatment System CWP 100 WROH	(K974899),
Gambro WRO 300H	(K093608)
Aquaboss EcoRO Dia	(K032004)

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	EcoRO DIA I+II (HT) SERIES		510(k)	5	page:2 of 8
	510(k) Summary		Author:	RD/Ln	
			Approved :	Kr	
			project:		
			18.03.2013	QM	

Classification panel:

Administrative Information	
Type of 510(k) submission:	Traditional
Medical device type:	Reverse Osmosis EcoRO Dia.
510(k) submitter:	Lauer Membran Wassertechnik GmbH Speichermatt 9 79599 Wittlingen Germany
Contact person:	Dr. Stephan Krietemeyer Title: Technical Director; VP Phone no. +49 7621 9270 15
Preference for continued confidentiality:	Yes, continued confidentiality
Classification regulation:	Water purification system for haemodialysis
Class:	II
Panel:	Gastroenterology/Urology
Product code:	FIP
FDA documents:	

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 haemodialysis.

- (a) Identification. A water purification system for haemodialysis is a device that is intended for use with a haemodialysis 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

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	EcoRO DIA I+II (HT) SERIES		510(k)	5 (page:3 of 8)
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			Approved :	Kr
			project:	
			18.03.2013	QM

Classification name:

Water purification system for haemodialysis (21 CFR 876 5665)

Device trade name:

EcoRO Dia I / EcoRO Dia II central water treatment systems

Common name:

Central Reverse Osmosis for Hemodialysis

Indications for use

510(k) Number (if known): K124059

Device Name: *Aquaboss® EcoRO I, Aquaboss® EcoRO I HT, Aquaboss® EcoRO II, Aquaboss® EcoRO II HT*

Indications for Use:

The Aquaboss® EcoRO I, EcoRO I HT, EcoRO Dia II and EcoRO Dia II HT are complete water treatment systems centered around reverse osmosis units of varying output which include recommended pretreatment components such as carbon filtration, backwash filters, softeners, and temperature blending valves and recommended post treatment such as final filtration intended for hemodialysis applications. The Aquaboss® water treatment systems are to be used at dialysis clinics or hospitals. The Aquaboss® EcoRO I, EcoRO I HT, EcoRO Dia II and EcoRO Dia II HT are intended to remove organic and inorganic substances and microbial contaminants from water. The treated water will then be used to prepare and dilute dialysate concentrate to form dialysate and/or rinse dialyzers for multiple uses and/or to prepare dilute solutions for reprocessing procedures in multiple-use dialyzers. The water treatment systems are designed to meet current AAMI/ISO and Federal (U.S.) standards.

The Aquaboss® water treatment systems come in the following configurations:

- (1) EcoRO I: Single-Pass / Single staged; Chemical Disinfection –
 - Catalogue numbers : 1106073 – 1109093 – 1106108 – 1106128 – 1106143 – 1106183 – 1106213 – 1106248 - 1106283 - 1106363
 - Description: Single staged reverse osmosis with permeate capacity of 700 l/h to 3600 l/h. Chemical disinfection possible. Pretreatment of potable water with components such as carbon filtration, backwash filters, softeners, and temperature blending valves. Post-treatment: Ringmain with optional final filtration for distribution of permeate to point of use.

- (2) EcoRO II Twin-Pass / Double Staged Chemical Disinfection
 - Catalogue numbers: 1107073 – 1107094 – 1107108 - 1107128 - 1107143 – 1107184 – 1107214 – 1107249 – 1107283 – 1107363
 - Dual/ Double staged reverse osmosis with permeate capacity of 700 l/h to 3600 l/h; Chemical Disinfection possible. Pretreatment of potable water with components such as carbon filtration, backwash filters, softeners, and temperature blending valves. Post-treatment: Ringmain with optional final filtration for distribution of permeate to point of use.

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			18.03.2013	QM

(3) EcoRO I HT Single-Pass / Single Staged Heat Disinfection

Catalogue numbers:

1106072 – 1106092 – 1106107 – 1106127 – 1106142 – 1106182 – 1106212 – 1106247 – 1106282 – 1106362

Description:

Single staged reverse osmosis with permeate capacity of 700 l/h to 3600 l/h.

Chemical disinfection possible

Hot water sanitization with Aquaboss® HotRinse SMART 10/ 20/30/40/60.

Pretreatment of potable water with components such as carbon filtration, backwash filters, softeners, and temperature blending valves.

Post-treatment: Ringmain with optional final filtration for distribution of permeate to point of use.

(4) EcoRO II HT Twin-Pass / Double Staged Chemical Disinfection

Catalogue numbers:

1107072 – 1107093 – 1107107 – 1107142 – 1107183 – 1107213 – 1107248 – 1107282 - 1107362

Description:

Dual/ Double staged reverse osmosis with permeate capacity of 700 l/h to 3600 l/h.

Chemical disinfection possible

Hot water sanitization with Aquaboss® HotRinse SMART 10/ 20/30/40/60.

Pretreatment of potable water with components such as carbon filtration, backwash filters, softeners, and temperature blending valves.

Post-treatment: Ringmain with optional final filtration for distribution of permeate to point of use.

Directions for use:

The system produces water for diluting hemodialysis concentrates according to AAMI ANSI ISO 13959: 2009 Water for hemodialysis and related therapies and AAMI ANSI ISO 11663:2009 Quality of dialysis fluid for hemodialysis and related therapies

The system output rate is 700l/h to 3600 l/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 ANSI ISO 13959: 2009 standard.

Ambient air temperature for **Aquaboss® EcoRO Dia I + II (HT)** is in the range of 5-40°C/41...104°F, max 75% relative humidity, non condensing

Device Description:

The **Aquaboss® EcoRO Dia I + II (HT)** Series Water Treatment System for Hemodialysis is a complete water purification system and consists of a reverse osmosis (RO) and pre-treatment. This product is an accessory device that is intended for use within the Hemodialysis facility to remove organic and inorganic substances and microbial contaminants from tap water used to dilute Dialysate concentrate to form Dialysate. This system has been designed to produce purified water as prescribed by AAMI ANSI ISO 13959: 2009 Water for hemodialysis and related therapies and provide adequate flow of the feed (tap) water and compliance with the existing drinking water standards. In order to optimize the performance of the RO system, the following items for pre-treatment can be utilized:

- 1) Softeners
- 2) Backwash filters
- 3) Organic Bed Service Carbon

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4) Raw Water Temperature Blending Value

Aquaboss® EcoRO Dia I + II (HT) operates 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 the microbiological quality of the permeate, 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 the Dialysis machine's via continuous flow distribution loop.
- The implementation of a secondary distribution loop which reduces dead space and pressure fluctuations.

Performance Monitoring:

The conductivity of the Permeate and the operating mode is continuously displayed on the LCD on the operator's panel. Alarm and error messages are displayed on the LCD. All readings for conductivities (raw water, permeate), flow (permeate, 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 pre flushed for 2 – 45 minutes. In this state the system carries out repeated backwashing operations and flushes concentrate down the drain.

Cleaning & Disinfection:

Aquaboss® EcoRO Dia I + II (HT) Series has a menu-guided cleaning and disinfection program. By following the displayed messages disinfection with peracetic acid disinfection products or heat can easily be carried out by the operator.

Standby operation

During standby the EcoRO Dia Series flushes automatically to reduce microbial growth in the system.

Material used

Pipework, pressure vessels:	Stainless steel AISI 316L (1.4404/1.4571)
Break Tank:	Polypropylene (PP)
Membranes, plugs/adapter	Polyamide (PA)
Seals/O-rings	Ethylene Propylene Diene Monomer (EPDM)
	Polytetrafluoroethylene (PTFE)
	Polyvinylidene fluoride (PVDF)

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Predicate Devices

The **Aquaboss**® EcoRO Dia I + II (HT) Water Treatment System is substantially equivalent to other water purification systems in commercial distribution in the United States to include the

- a) Gambro Central Water Treatment System CWP 100 WROH (K974899),
- b) Gambro WRO 300H (K093608)
- c) Aquaboss EcoRO Dia (K032004)

- All systems utilize reverse osmosis for purification of water to be used for hemodialysis
- All systems utilize a polyamide, thin film composite, spiral wound membrane for hemodialysis
- All systems are intended to be used for water purification for hemodialysis.
- All systems use substantially equivalent water contact materials for pumps, tubing and other fittings.
- All systems can utilize chemical disinfection using peracetic acid disinfection products
- **Aquaboss**® EcoRO Dia I+II (HT) series as well as Gambro WRO 300H can optionally utilize heat for the disinfection of the RO membrane
- **Aquaboss**® EcoRO Dia I+II (HT) series as well as Gambro Central Water Treatment System CWP 100 WROH can optionally utilize heat for the disinfection of the connected ring main
- All system display poor water quality and pressure alarms on a display
- All systems monitor water quality on digitally displays
- As a beneficial feature **Aquaboss**® EcoRO Dia I+II (HT) may be equipped with a second membrane barrier to provide fully redundant 100% capacity. The optional second RO stage is completely flushed through during standard operation. That prevents the risk of microbiological growth during standby that usually present in alternating central RO systems where one RO is in standby while the second RO is operational.

We therefore consider the **Aquaboss**® EcoRO Dia I + II (HT) Water Treatment to be substantially equivalent to the following approved devices.

Intended use:

Device that is intended for use with a hemodialysis system to remove organic and inorganic substances and microbial contaminants from water used to dilute dialysate concentrate to form dialysate. This device may include a water softener, sediment filter and carbon filter

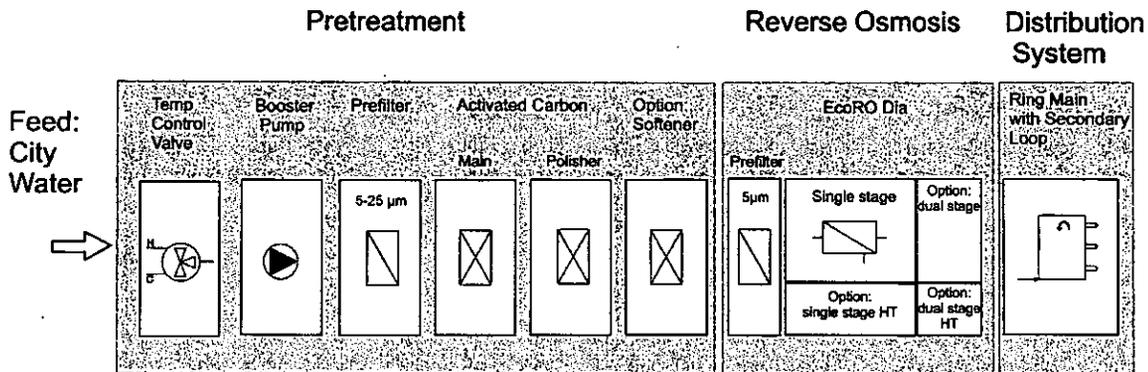
Aquaboss® EcoRO Dia I + II (HT) Water Treatment System is an accessory device designed to safely and effectively provide water purification for use in Hemodialysis applications.

The product water produced will meet the minimum water quality requirements as specified by the AAMI ANSI ISO standard 13959:2009 and AAMI ANSI ISO standard 23500:2011 when used as directed. Dependent on feed water quality, this unit may be used in conjunction with other approved water treatment components. Enclosed below is a chart indicating the physical differences of the EcoRO Dia Series:

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Pre treatment and EcoRO Dia Series Diagram with optional dual stage RO and heat disinfection module.



Technological Characters

Comparing the proposed device to the predicate devices, some similarities and differences are noted in the design employed to accomplish the same intended use: All systems utilize reverse osmosis for purification of water to be used for Hemodialysis. All systems utilize a polyamide, thin film composite, and spiral wound membrane for Hemodialysis. All systems are intended to be used for water purification for Hemodialysis. All systems use substantially equivalent water contact materials for pumps, tubing and other fittings. All systems can utilize chemical disinfection using peracetic acid disinfection products or heat disinfection as outlined in the AAMI ANSI ISO standard 23500:2011. All systems display poor water quality and pressure alarms on a display. All systems monitor water quality on digitally displays.

The **Aquaboss®** EcoRO Dia I + II (HT) Multi-Patient Water Treatment System may combine features of the predicate devices (heat disinfection of the ring main and heat disinfection of the RO membrane) as optional features.

An additional feature of **Aquaboss®** EcoRO Dia I + II (HT) is the optional second RO stage. This second stage works as a redundant backup RO that is permanently flushed and flown through. As an additional benefit this configuration adds a second permeate purification step to the system to ensure best microbiological and chemical water quality.

Assessment of non-clinical performance data

The non clinical testing applied to **Aquaboss®** EcoRO Dia I+II (HT) water purification units equipped with Software 1.04, in order to determine substantial equivalence with the predicate device included:

- Validation and Verification of Software including all options for single and double staged RO systems as well as HT (hot disinfection of RO membranes and ring main) in system integration testing as well as alarm and error testing. (Internal software and performance tests)
- Disinfection chemical and heat (Internal software and performance tests)
- Membrane performance (flux, rejection) and system performance derived from QA testing demonstrating that system performances are equivalent with predicate devices. Substantial Equivalence with predicate devices
- Microbiological stability for bacterial counts and endotoxins according to AAMI AISI ISO standard 13959:2009; AAMI AISO ISO standard 23500:2011
- Leachable and extractable testing (Biocompatibility External Test laboratory and predicate devices)
- Electrical safety (IEC 61010; cUL_{US}; ANSI/UL61010 external test laboratory)

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- Electromagnetic compatibility testing according to IEC 6061-1-2 (External test laboratory)
- Functional safety (according to ISO 14971)
- Ergonomics and usability (IEC 62366 & Risk management according to ISO 14971)
- Maintenance and reliability (Long term market performance Europe and SEA)

The assessment was performed by internal and external independent personnel

Conclusion

Testing results demonstrate that **Aquaboss®** EcoRO Dia I+II (HT) water purification units meets all performance specifications equivalent to the predicate devices. In addition external and internal test results indicate that **Aquaboss®** EcoRO Dia I+II (HT) comply with all requirements stated in applicable recognized consensus standards for water treatment for hemodialysis. Therefore we believe that **Aquaboss®** EcoRO Dia I+II (HT) meets all AAMI/ANSI/ISO standards and Federal Regulations that are applicable for water purification system for haemodialysis [21CFR876.5665]

Beyond that, heat disinfection of the RO membranes did not affect safety or membrane performance and performed equivalent to predicate device disinfection for the purpose of ensuring low microbiological counts.

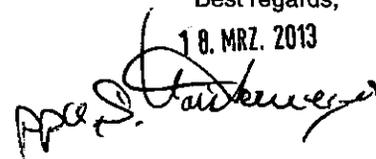
In addition to standard tests applicable for reverse osmosis testing specific to heat disinfection of the membrane included:

- Biocompatibility testing of extract from the hydraulic flow path of product contact material
- Validation of heat disinfection procedure in regards to temperature and contact time
- Long term evaluation of microbiological performance of the RO systems from performance data of European installations of these systems.

Test results demonstrate that the device is as safe, as effective and performs well or better than the predicate device.

Best regards,

18. MRZ. 2013



Dr. Stephan Krietermeyer

Technical Director / VP.

Lauer Membran Wassertechnik GmbH

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Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

March 25, 2013

Lauer Membran Wassertechnik GmbH
% Dr. Stephan Krietemeyer
Technical Director, VP
9 Speichermatt
WITTLINGEN BW 79599
GERMANY

Re: K124059

Trade/Device Name: Aquaboss® EcoRO I, Aquaboss® EcoRO I HT,
Aquaboss® EcoRO II, Aquaboss® EcoRO II HT

Regulation Number: 21 CFR§ 876.5665

Regulation Name: Water purification system for hemodialysis

Regulatory Class: II

Product Code: FIP

Dated: December 27, 2012

Received: December 31, 2012

Dear Dr. Krietemeyer:

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. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

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); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); 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.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to <http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucml15809.htm> for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

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) 796-7100 or at its Internet address <http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,

Herbert  Lerner -S

for
Benjamin R. Fisher, Ph.D.
Director
Division of Reproductive, Gastro-Renal,
and Urological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use Form

510(k) Number (if known): K124059

Device Name: *Aquaboss*[®] EcoRO I, *Aquaboss*[®] EcoRO I HT,
Aquaboss[®] EcoRO II, *Aquaboss*[®] EcoRO II HT

Indications for Use:

The *Aquaboss*[®] EcoRO I, EcoRO I HT, EcoRO Dia II and EcoRO Dia II HT are complete water treatment systems centered around reverse osmosis units of varying output which include recommended pretreatment components such as carbon filtration, backwash filters, softeners, and temperature blending valves and recommended post treatment such as final filtration intended for hemodialysis applications.

The *Aquaboss*[®] water treatment systems are to be used at dialysis clinics or hospitals. The *Aquaboss*[®] EcoRO I, EcoRO I HT, EcoRO Dia II and EcoRO Dia II HT are intended to remove organic and inorganic substances and microbial contaminants from water. The treated water will then be used to prepare and dilute dialysate concentrate to form dialysate and/or rinse dialyzers for multiple uses and/or to prepare dilute solutions for reprocessing procedures in multiple-use dialyzers.

The water treatment systems are designed to meet current AAMI/ISO and Federal (U.S.) standards.

The *Aquaboss*[®] water treatment systems come in the following configurations:

(1) EcoRO I: Single-Pass / Single staged; Chemical Disinfection –

Catalogue numbers :

1106073 – 1109093 – 1106108 – 1106128 – 1106143 – 1106183 – 1106213 –
1106248 - 1106283 - 1106363

Description:

Single staged reverse osmosis with permeate capacity of 700 l/h to 3600 l/.

Chemical disinfection possible.

Pretreatment of potable water with components such as carbon filtration, backwash filters, softeners, and temperature blending valves.

Post-treatment: Ringmain with optional final filtration for distribution of permeate to point of use.

(2) EcoRO II Twin-Pass / Double Staged Chemical Disinfection

Catalogue numbers:

1107073 – 1107094 – 1107108 - 1107128 - 1107143 – 1107184 – 1107214 – 1107249
– 1107283 – 1107363

Dual/ Double staged reverse osmosis with permeate capacity of 700 l/h to
3600 l/;

Chemical Disinfection possible.

Pretreatment of potable water with components such as carbon filtration, backwash filters, softeners, and temperature blending valves.

Post-treatment: Ringmain with optional final filtration for distribution of permeate to point of use.

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(3) EcoRO I HT Single-Pass / Single Staged Heat Disinfection

Catalogue numbers:

1106072 – 1106092 – 1106107 – 1106127 – 1106142 – 1106182 – 1106212 –
1106247 – 1106282 – 1106362

Description:

Single staged reverse osmosis with permeate capacity of 700 l/h to 3600 l/.

Chemical disinfection possible

Hot water sanitization with Aquaboss® HotRinse SMART 10/ 20/30/40/60.

Pretreatment of potable water with components such as carbon filtration, backwash filters, softeners, and temperature blending valves.

Post-treatment: Ringmain with optional final filtration for distribution of permeate to point of use.

(4) EcoRO II HT Twin-Pass / Double Staged Chemical Disinfection

Catalogue numbers:

1107072 – 1107093 – 1107107 – 1107142 – 1107183 – 1107213 – 1107248 –
1107282 - 1107362

Description:

Dual/ Double staged reverse osmosis with permeate capacity of 700 l/h to 3600 l/.

Chemical disinfection possible

Hot water sanitization with Aquaboss® HotRinse SMART 10/ 20/30/40/60.

Pretreatment of potable water with components such as carbon filtration, backwash filters, softeners, and temperature blending valves.

Post-treatment: Ringmain with optional final filtration for distribution of permeate to point of use.

Herbert P. Lerner -S

(Division Sign-Off)

**Division of Reproductive, Gastro-Renal, and
Urological Devices**

K124059

510(k) Number _____

Prescription Use YES
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use: n/a
(21 CFR 801 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

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