Gambro Renal Products, Inc.
14143 Denver West Parkway, Suite 400
Lakewood, Colorado 80401

JUL 29 2010

510(K) SUMMARY

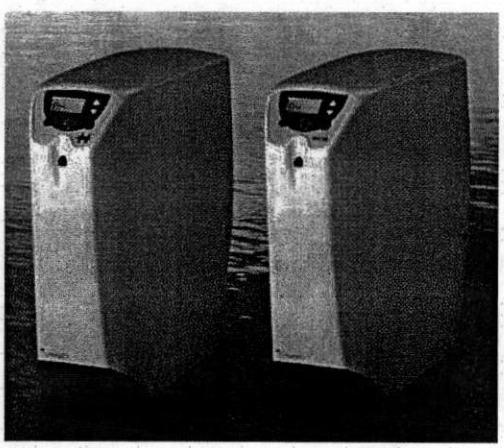
Submitter's Name	Gambro Renal Products, Inc.
Address	14143 Denver West Parkway, Suite 400 Lakewood, Colorado 80401
Establishment Registration Number	2087532
Contact Person	Kae Miller, Regulatory Affairs Manager
Telephone Number	303.222.6724
Fax Number	303.222.6916
Date of Summary	July 23, 2010

Device	
Name of the Device	WRO 300 Catalogue Number: 107364
	WRO 300 H Catalogue Number: 107365
Common or Usual Name	Water Purification Unit
Classification Name	Subsystem, Water treatment
Device Class	II
Product Code	78FIP
Regulation Number	876.5665

Gambro Renal Products, Inc.
14143 Denver West Parkway, Suite 400
Lakewood, Colorado 80401

510(k) SUMMARY, continued

Legally Marketed Device (Predicate Device)	
Name of the Device	Gambro WRO 300 Water Purification System For Hemodialysis
Catalogue Number	107364
Classification Name	Subsystem, Water treatment
Device Class	II
Product Code	78FIP
Regulation Number	876.5665
510(k) number	K042797



	WRO 300	WRO 300 H
Weight	29 kg	33 kg
Height	563 mm	563 mm
Depth	Max 520 mm Footprint 380 mm	Max 520 mm Footprint 380 mm
Width	Max 205 mm Footprint 185 mm	Max 205 mm Footprint 185 mm
Internal fluid volume	Approximately 3.5 liters excluding the product water loop	

The Gambro WRO 300 and WRO 300 H Water Purification Units are dialysis accessories that produce water through reverse osmosis for one hemodialysis equipment.

They are both designed to maintain the low microbiological level in their flow path by the use of regular disinfection as a regular maintenance. Both WRO 300 and WRO 300 H Water Purification Units are designed with chemical disinfection capability. The WRO 300 H Water Purification Unit is also designed with heat disinfection capability.

WRO 300 or WRO 300 H Water Purification Unit is intended for use in conjunction with one dialysis machine, provided that the input flow and pressure demands correspond to the output of the WRO 300 or WRO 300 H Water Purification Unit.

WRO 300 and WRO 300 H Water Purification Units utilize the Reverse Osmosis Principle. A high pressure pump forces the water through the RO membrane. The product water is further distributed to the dialysis machine.

Gambro Renal Products, Inc.
14143 Denver West Parkway, Suite 400
Lakewood, Colorado 80401

Reverse osmosis (RO) is a membrane process that is the most widely used technique for purification of water for dialysis. When the feed water is in contact with the semipermeable membrane (the most vital part of the system) and a high pressure is applied, water will flow through the membrane to the product water side. Most of the other constituents (dissolved salts, particles, bacteria and pyrogens) will remain on the feed water side of the membrane and be flushed to drain as reject water. The membrane material used for the WRO 300 and WRO 300 H Water Purification Units are Polyamide Thin-Film Composite.

An acceptable quality of the feed water is required. The feed water is usually pretreated with such as active carbon filters, softener, and particle filters before it is supplied to the WRO 300 or WRO 300 H Water Purification Unit. Depending on the local water quality and regulations different pretreament equipment may be required.

Gambro WRO 300 and WRO 300 H Water Purification units contain the same software package (version P4.2) which is intended for controlling water production and disinfection / cleaning of the flow path of the WRO.

The software also supports Heat Disinfection in the WRO 300 H Water Purification Unit.

INDICATIONS FOR USE WRO 300:

The Gambro WRO 300 Water Purification Unit is intended to be used as a dialysis accessory to produce water through reverse osmosis for one hemodialysis equipment.

The WRO 300 can be connected to hemodialysis equipment used both in hospitals and in home environments, in conjunction with appropriate pre and post treatment units, as a part of a water treatment system designed to meet current AAMI and Federal (U.S.) standards.

INDICATIONS FOR USE WRO 300 H:

The Gambro WRO 300 H Water Purification Unit is intended to be used as a dialysis accessory to produce water through reverse osmosis for one hemodialysis equipment.

The WRO 300 H can be connected to hemodialysis equipment used both in hospitals and in home environments, in conjunction with appropriate pre and post treatment units, as a part of a water treatment system designed to meet current AAMI and Federal (U.S.) standards.

510(k) SUMMARY, continued

DEVICE COMPARISON TABLE

In the following table the WRO 300 and the WRO 300 H are compared with the predicate device WRO 300 (K042797).

	PREDICATE WRO 300 (K042797) SW1.0	WRO 300 SW P4.2	WRO 300 H SW P4.2
Indications for Use	The Gambro WRO 300 Water Purification System is intended to be used as a dialysis accessory device in conjunction with one dialysis machine to produce water used to prepare and dilute dialysis concentrate to form dialysis fluid by using the reverse osmosis concept.	The Gambro WRO 300 Water Purification Unit is intended to be used as a dialysis accessory to produce water through reverse osmosis for one hemodialysis equipment. The WRO 300 can be connected to hemodialysis equipment used both in hospitals and in home environments, in conjunction with appropriate pre and post treatment units, as a part of a water treatment system designed to meet current AAMI and Federal (U.S.) standards.	The Gambro WRO 300 H Water Purification Unit is intended to be used as a dialysis accessory to produce water through reverse osmosis for one hemodialysis equipment. The WRO 300 H can be connected to hemodialysis equipment used both in hospitals and in home environments, in conjunction with appropriate pre and post treatment units, as a part of a water treatment system designed to meet current AAMI and Federal (U.S.) standards.
Feed Water Supply	*Input:*3.0 l/min required *Pressure:*0.2 to 0.8 MPa *Temperature:* +5 to +30˚C *Hardness:* recommendation < 1 °dH (20 ppm as CaCO3)	*Input: Min.* 3.0 l/min required *Pressure:*0.15 to 0.8 MPa during operation *Temperature:* +5 to +30˚C *Hardness:* recommendation < 1 °dH (20 ppm as CaCO3)	*Input: Min.* 3.0 l/min required *Pressure:*0.15 to 0.8 MPa during operation *Temperature:* +5 to +30˚C *Hardness:* recommendation < 0.3 °dH (6 ppm as CaCO3)

K093608
PAGE 4 OF 6

	PREDICATE WRO 300 (K042797) SW1.0	WRO 300 SW P4.2	WRO 300 H SW P4.2
Product water	*Output flow:* Minimum 1.1 l/min at 10°C. *Product water loop:* Maximum 20 meters (2 x 10m). Designed for flexible, rein-forced tubing 8 mm x 2.5 mm. *Product water pressure:* 0.12 to 0.6 MPa during RUN mode. *Rejection rates:* Total dissolved salts: >95%. Bacteria and endotoxin: >99%.	*Output flow:* Minimum 1.1 l/min at 10°C. *Product water loop:* Maximum 20 meters (2 x 10m). Designed for flexible, rein-forced tubing. *Product water pressure:* 0.12 to 0.6 MPa during RUN mode. *Rejection rates:* Total dissolved salts: >96%. Bacteria and endotoxin: >99%.	*Output flow:* Minimum 1.2 l/min at 10°C. *Product water loop:* Maximum 2 meters (2 x 1m). Designed for flexible, rein-forced tubing. *Product water pressure:* 0.12 to 0.6 MPa during RUN mode. *Rejection rates:* Total dissolved salts: >96%. Bacteria and endotoxin: >99%.
Drain requirements	*Operation:* 1.2 ±0.1 l/min. *Peak flow (rinse):* 3.0 l/min	*Operation:* 1.2 ±0.1 l/min. *Peak flow (rinse):* 3.0 l/min	*Operation:* 1.2 ±0.1 l/min. *Peak flow (rinse):* 3.0 l/min
Reverse osmosis membrane	*Material:* Polyamide, thin film composite. *Configuration:* Spiral wound. *pH-tolerance:* 2-11	*Material:* Polyamide, thin film composite. *Configuration:* Spiral wound. *pH-tolerance:* 2-11	*Material:* Polyamide, thin film composite. *Configuration:* Spiral wound. *pH-tolerance:* 2-11
Disinfection and cleaning	Chemical disinfection. Cleaning.	Chemical disinfection. Cleaning.	Chemical disinfection. Cleaning. Heat disinfection.
Ambient	*Temperature:* + 10 to + 40 °C	*Temperature:* + 10 to + 40 °C	*Temperature:* + 10 to + 40 °C

K093608
PAGE 5 OF 6

Gambro Renal Products, Inc.
14143 Denver West Parkway, Suite 400
Lakewood, Colorado 80401

510(k) SUMMARY, continued

Assessment of non-clinical performance data

The non-clinical testing applied to the Gambro WRO 300 and WRO 300 H Water Purification Units, equipped with the software version P4.2, in order to determine the substantial equivalence with the predicate device, included:

- verification and validation of the software changes, with static and dynamic software testing, and regression testing,
- verification and validation of the functional, performance and safety requirements related to
    - the membrane life expectancy;
    - user interface/control system
    - disinfection both chemical and heat
    - physical ergonomics
    - maintenance and reliability
- compliance with international standard on electrical safety (IEC 60601-1),
- compliance with international standard on electromagnetic compatibility (IEC 60601-1-2).

The assessment was performed by internal and external independent personnel with the appropriate skills.

Assessment of clinical performance data

Not applicable for this submission.

Conclusion

Testing results of the R.O. Membrane (rejection of total dissolved salts, bacteria and endotoxins), output flow, water pressure, drain flow, electrical safety (in accordance to IEC 60601-1), electromagnetic compatibility (in accordance to IEC 60601-1-2), biocompatibility (in accordance with ISO 10993-5, ANSI/AAMI RD62, ISO/FDIS 13959, European Pharmacopoeia 5th ed.), and software validation demonstrate that the WRO 300 and WRO 300H with software version 4.2 meets all performance specifications equivalent to the predicate device.

In addition, testing conducted on the WRO 300H confirmed that heat disinfection did not affect safety or membrane performance, and performed equivalent to predicate device disinfection capability for the purpose of ensuring low microbiological level in the flow path. In addition to standards tests applicable for reverse osmosis, testing specific to the heat disinfection included:

- Biocompability test (in accordance with ISO 10993-5, ANSI/AAMI RD62, ISO/FDIS 13959, European Pharmacopoeia 5th ed.) of extract from the hydraulic flow path after RO membrane
- Validation of heat disinfection procedure in regards to temperature in flow path during Heat disinfection (coolest spot in flow path at least 80° C, with 5 log reduction for all positions)
- Evaluation of Microbial retention by the RO membrane

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
10903 New Hampshire Avenue
Document Mail Center - WO66-G60
Silver Spring, MD 20993-0002

Ms. Kae Miller
Regulatory Affairs Manager
Gambro Renal Products, Inc.
14143 Denver West Parkway, Suite 400
LAKEWOOD CO 80401

JUL 29 2010

Re: K093608
Trade/Device Name: WRO 300 and WRO 300 H
Regulation Number: 21 CFR §876.5665
Regulation Name: Water purification system for hemodialysis
Regulatory Class: II
Product Code: FIP
Dated: July 26, 2010
Received: July 27, 2010

Dear Ms. Miller:

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/ucm115809.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,

Janine M. Morris
Acting Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

K093608

Gambro Renal Products, Inc.
14143 Denver West Parkway, Suite 400
Lakewood, Colorado 80401

Traditional 510(k)
WRO 300 and WRO 300 H

Indications for Use

510(k) Number (if known): K093608

JUL 29 2010

Device Name: WRO 300

Indications for Use WRO 300:

The Gambro WRO 300 Water Purification Unit is intended to be used as a dialysis accessory to produce water through reverse osmosis for one hemodialysis equipment.

WRO 300 can be connected to hemodialysis equipment used both in hospitals and in home environments, in conjunction with appropriate pre and post treatment units, as a part of a water treatment system designed to meet current AAMI and Federal (U.S.) standards.

Device Name: WRO 300 H

Indications for Use WRO 300 H:

The Gambro WRO 300 H Water Purification Unit is intended to be used as a dialysis accessory to produce water through reverse osmosis for one hemodialysis equipment.

WRO 300 H can be connected to hemodialysis equipment used both in hospitals and in home environments, in conjunction with appropriate pre and post treatment units, as a part of a water treatment system designed to meet current AAMI and Federal (U.S.) standards.

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K093608

Prescription Use X AND/OR Over-The-Counter Use
(Part 21 CFR 801 Subpart D) (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)