DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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

September 23, 2015

Specialty Water Technologies
Alex Clark
Compliance Manager
1020 Industrial Drive
Orlinda, TN 37141

Re: K151637
Trade/Device Name: UPT Series Medical Reverse Osmosis Water Treatment System
Regulation Number: 21 CFR 876.5665
Regulation Name: Water purification system for hemodialysis
Regulatory Class: II
Product Code: FIP
Dated: August 21, 2015
Received: August 24, 2015

Dear Alex Clark,

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 contact the Division of Industry and Consumer Education 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. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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 Industry and Consumer Education 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,

Benjamin R. Fisher -S

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

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*

K151637

Device Name
UPT Series Medical Reverse Osmosis Water Treatment System

Indications for Use *(Describe)*

UPT Series Medical Reverse Osmosis Water Treatment System is intended to be used to remove organic and inorganic contaminants from a tap water supply to dilute a dialysate concentrate for hemodialysis treatments, as well as for use for dialyzer reprocessing and dialysis equipment disinfecting and rinsing.

This System is strictly for multi patient use, such as for a dialysis clinic or hospital serving multiple patients with a Central Water Purification System and is intended for use only with conventional hemodialysis treatments. It is not intended for use with high-flux, CRRT, or any other form of dialysis.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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510(k) Summary

510(k) Number: _____

Manufacturer: Specialty Water Technologies

Address: 1020 Industrial Drive
Orlinda, TN 37141
(615) 654-4441

Official Contact: Alex Clark
Compliance Manager

Trade Name: UPT Series Medical Reverse Osmosis Water Treatment System
Common Name: Water Purification System
Classification Name: Water Purification System for Hemodialysis
Product Code: 78 FIP
Device Class: II
Classification Reg: 876.5665

Specialty Water Technologies has provided the following information to the US Food and Drug Administration to support substantial equivalence of the UPT Series Medical Reverse Osmosis (RO) Water Purification System to other RO water purification systems currently cleared for sale in the U.S.

1. **Device Description**
   The UPT Series Medical Reverse Osmosis Water Treatment System is an accessory device that is intended for use with hemodialysis applications and is intended to remove organic and inorganic substances and microbial contaminates from tap water used to dilute dialysis concentrate to form dialysate. The UPT Series Medical Reverse Osmosis Water Treatment System will produce water as prescribed by the Association for the Advancement of Medical Instrumentation (AAMI) Standard ANSI/AAMI/ISO 13959:2014 Water for Hemodialysis and Related Therapies provided adequate flow rate of the feed (tap) water and compliance with existing drinking water standards and proper pre-treatment.

2. **Intended Use**
   UPT Series Medical Reverse Osmosis Water Treatment System is intended to be used to remove organic and inorganic contaminants from a tap water supply to dilute a dialysate concentrate for hemodialysis treatments, as well as for use for dialyzer reprocessing and dialysis equipment disinfecting and rinsing.

This System is strictly for multi patient use, such as for a dialysis clinic or hospital serving multiple patients with a Central Water Purification System and is intended for use only with conventional hemodialysis treatments. It is not intended for use with high-flux, CRRT, or any other form of dialysis.

3. Substantial Equivalence to Predicate Device

Specifications	UPT Series Medical Reverse Osmosis Water Treatment System	Predicate Devices	
		Matrix Series Digital Reverse Osmosis	Complete Water System Models MD610, 620, 630 and 640
Manufacturer	Specialty Water Technologies	Better Water, Inc	Isopure Corporation
510(k) Number	-	K051620	K041163
Decision Date	-	11/18/2005	10/7/2004
Classification	876.5665, Class II	876.5665, Class II	876.5665, Class II
Product Code	78 FIP	78 FIP	78 FIP
Water Contact Materials	FDA-NSF Compliant	FDA-NSF Compliant	FDA-NSF Compliant
Pre-Treatment Options	Based upon site specific feed water chemical analysis	Based upon site specific feed water chemical analysis	Based upon site specific feed water chemical analysis
	Feed water Pre-Treatment may include:	Feed water Pre-Treatment may include:	Feed water Pre-Treatment may include:
	Carbon Filtration	Carbon Filtration	Carbon Filtration
	Softeners	Softeners	Softeners
	Temperature Control	Temperature Control	Temperature Control
	Pressure Compensation	Pressure Compensation	Pressure Compensation
	Special Filtration	Special Filtration	Special Filtration
	Ultra-Violet (UV)	Ultra-Violet (UV)	Ultra-Violet (UV)
Operational Features	Electronic Touch Screen Interface	Electronic Touch Screen Interface	Electronic Touch Screen Interface
	All components mounded on an open frame for accessibility	All components mounted on an open frame for accessibility	All components mounted on an open frame for accessibility
	Electronic Monitoring of:	***Electronic Monitoring of:***	***Electronic Monitoring of:***
	Feed Water Pressure / Flow	Feed Water Pressure / Flow	Feed Water Pressure
	Product Water Pressure / Flow	Product Water Pressure / Flow	Product Water Pressure
	Membrane Feed Pressure	Membrane Feed Pressure	Membrane Feed Pressure
	Pump Pressure	Pump Pressure	Pump Pressure
	Reject Water Pressure / Flow	Reject Water Pressure / Flow	Reject Water Pressure / Flow
	Product Water Conductivity	Product Water Conductivity	Product Water Conductivity
	Feed Water Conductivity	Feed Water Conductivity	Feed Water Conductivity
Safety Features	100% Diversion to drain above product conductivity set-point	100% Diversion to drain above product conductivity set-point	100% Diversion to drain above product conductivity set-point
	Low Supply Pressure Alarm	Low Supply Pressure Alarm	Low Supply Pressure Alarm
	High Product Water Conductivity Alarm	High Product Water Conductivity Alarm	High Product Water Conductivity Shut Down
	High Supply Water Temperature Shut Down	High Supply Water Temperature Shut Down	High Supply Water Temperature Shut Down
	Power Disturbance Alarm	Power Disturbance Alarm	Power Disturbance Alarm
	Remote Alarm (Nurses Station)	Remote Alarm (Nurses Station)	Remote Alarm (Nurses Station)
Post-Treatment	May include 0.5 micron or better ultra-filtration	May include 0.5 micron or better ultra-filtration	May include 0.5 micron or better ultra-filtration
Performance	Delivery of AAMI Standard Water	Delivery of AAMI Standard Water	Delivery of AAMI Standard Water

4. Safety and Effectiveness

The intended use and technological characteristics of the UPT Series Medical Reverse Osmosis Water Treatment System are similar or equivilant to the predicate devices indicated. Any differences between the device and the predicate devices have no significant influence on the safety or effectiveness of the product.

5. Clinical Performance Data

Not required for determination of substantial equivilance for this type and class of device.

6. Electromagnetic Compatibility & Safety

The water system does not contain any wifi, wireless or other transmitting or receiving devices. Any electrical connections between components are wired to include any remote alarms.

The electrical control components purchased and used in the construction of the components used for this water system comply with:

EN/IEC 61000-4-2 Electrostatic Discharges
EN/IEC 61000-4-3 Radiated Fields and Transients / Burst
EN/IEC 61000-4-4 Electrical Fast Transients / Burst
EN/IEC 61000-4-8 Magnetic Field
UL Approved / Recognized for safety

All pumps used are UL recognized (UR) and CSA Approved for safety

7. Conclusion Drawn from Clinical and Nonclinical Test Data

As compared with the predicate devices, K051620 and K041663, the UPT Series Medical Reverse Osmosis Water Treatment System will produce water that will meet the minimum water quality requirements as specified by Association for the Advancement of Medical Instrumentation (AAMI) standard ANSI/AAMI/ISO 13959:2014, Water for Hemodialysis and Related Therapies; and ANSI/AAMI/ISO 26722:2014, Water Treatment Equipment for Hemodialysis Applications and Related Therapies, when used as directed.