



March 17, 2025

Specialty Water Technologies, Inc.
% Mark Spreeman
Regulatory, Quality, and Compliance Consultant
DuVal & Associates
Suite 1820, Medical Arts Building
825 Nicollet Mall
Minneapolis, MN 55402

Re: K250514
Trade/Device Name: UPT Series Medical RO Water Treatment System
Regulation Number: 21 CFR§ 876.5665
Regulation Name: Water Purification System For Hemodialysis
Regulatory Class: II
Product Code: FIP
Dated: February 21, 2025
Received: February 21, 2025

Dear Mark Spreeman:

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 (the 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. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database available at <https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm> identifies combination product submissions. 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (<https://www.fda.gov/media/99812/download>) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (<https://www.fda.gov/media/99785/download>).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 4, Subpart B) for combination products (see <https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products>); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at <https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system>.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems>.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (<https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance>) and CDRH Learn (<https://www.fda.gov/training-and-continuing-education/cdrh-learn>). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (<https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice>) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Maura Rooney -S

Maura Rooney
Assistant Director
DHT3A: Division of Renal, Gastrointestinal,
Obesity and Transplant Devices
OHT3: Office of GastroRenal, ObGyn,
General Hospital and Urology Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

Indications for Use

Submission Number (if known)

K250514

Device Name

UPT Series Medical RO 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 for multi patient use, such as for a dialysis clinic or hospital serving multiple patients with a Central Water Purification System.

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) Owner: Specialty Water Technologies, Inc.
104 Flex Ave.
Portland, TN 37149
Contact: Alex Clark
615-654-4441
Date prepared: February 20, 2025

Device Name: Trade Name: UPT Series Medical RO Water Treatment System
Common Name: Subsystem, Water Purification
Classification Name: Water purification system for hemodialysis
Regulation: 21 CFR §876.5665
Regulatory Classification: 2
Product Code: FIP

Predicate Devices: **Primary:** UPT Series Medical Reverse Osmosis Water Treatment System (151637) **Additional:** Isopure Complete Water Purification System (K041163)

Device Description:

The UPT Series Medical Reverse Osmosis Water Treatment System and its components consisting of; pre-treatment, reverse osmosis, post-treatment, and the product water distribution components, are designed to remove microbiological, organic, and inorganic contaminants from the tap water to supply dialysis machines for the preparation of dialysate solutions for hemodialysis treatments.

Pretreatment components can include a tap water boosting system, blending valve, sediment filtration, carbon removal filters, water softeners, and all the necessary interconnecting plumbing. The purpose of this part of the system is to ensure that properly conditioned water is supplied to the reverse osmosis machine to ensure its safe and trouble-free operation.

After the tap water has been pre-treated, it then enters the R.O. (reverse osmosis), where total dissolved solids are removed to pertinent water quality standards. This is accomplished by utilizing a membrane separation process, whereby the incoming water is separated into a product stream, and a concentrate stream. The molecular weight cut-off determines what and how many contaminants are passed through into the product stream. R.O.s used for this application typically remove 95-99% of all total dissolved solids and bacteria.

The post treatment and product water distribution part of the system is in place to store, provide additional purification if needed, and deliver the purified water to wherever needed. These components can include items such as a storage tank, final filters (for bacteria and endotoxins), and delivery pumps and controls. Some systems can also utilize an ultraviolet light for additional disinfection properties if needed.

Indications for 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 for multi patient use, such as for a dialysis clinic or hospital serving multiple patients with a Central Water Purification System.

Substantial Equivalence Comparison with the Predicate Devices

Indications for Use are identical to the primary predicate device with the exception of excluding limitations for certain hemodialysis applications that existed in the predicate. These limitations were inadvertently incorporated into the Indications for Use and have now been corrected. No other changes have been made to the Indications for Use. This is a minor change with no impact on the use of the device, and so does not constitute a new intended use.

The technological characteristics between the subject device and both predicates are identical in Regulation Number, Product Code, Pre-Treatment Options, Operational Features, Safety Features, Post-Treatment, and Performance in providing water purification systems for hemodialysis. Hence, there are no changes between the subject device and predicates that would raise different questions of safety or effectiveness.

As set out in section 513(i) of the FD&C Act, a determination of substantial equivalence requires: 1) the same intended use, and 2) either the same technological characteristics or differences in technological characteristics that do not raise different questions of safety or effectiveness. Both of these conditions have been met and support a determination of substantial equivalence.

Non-Clinical Performance Data

This modification is to the current UPT Series Medical Reverse Osmosis Water Treatment System (primary predicate), and is specific to clarifying the Indications for Use. No verification or validation performance testing was required for this labeling update and the system remains compliant to its current specifications and requirements.

Conclusion

Inclusive of this labeling update, the UPT Series Medical Reverse Osmosis Water Treatment System continues to meet all of its established acceptance criteria that were based upon performance of the primary predicate device. This demonstrates that the device function is as safe, as effective, and performs as well as the primary predicate device. The information provided supports substantial equivalence of the UPT Series Medical Reverse Osmosis Water Treatment System to the predicate devices.