January 5, 2018

Cantel
Katlin Adamski
Regulatory Affairs Specialist
14550 28th Avenue North
Minneapolis, MN 55447

Re: K171099
Trade/Device Name: EON Portable Reverse Osmosis Water Purification System
Regulation Number: 21 CFR§ 876.5665
Regulation Name: Water Purification System For Hemodialysis
Regulatory Class: II
Product Code: FIP
Dated: December 6, 2017
Received: December 7, 2017

Dear Katlin Adamski:

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.

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.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Charles Viviano -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

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)*
K171099

Device Name
EON Portable Reverse Osmosis Water Purification System

Indications for Use *(Describe)*
The EON Portable Reverse Osmosis Water Purification System is intended to be used as a dialysis accessory to produce water through reverse osmosis for use with hemodialysis equipment. EON can be connected to hemodialysis equipment used in hospitals, clinics and in home environments, in conjunction with the appropriate pre and post treatment units, as part of a water treatment system designed to meet current AAMI and Federal (U.S.) standards.

EON has optional heat disinfection cycles intended to disinfect the reverse osmosis (RO) machine and product loop, and connection tubing to the hemodialysis machine. EON's heat disinfection cycle to disinfect the connection tubing (heat forward cycle) is intended to be used only with hemodialysis machines which contain their own heat disinfection cycles and hence are able to tolerate high temperatures. EON is not intended to heat disinfect the hemodialysis machine.

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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CANTEL

Section 05 - 510(k) Summary

Manufacturer: Mar Cor – A Cantel Medical Company

Address: 14550 28th Avenue North
Minneapolis, MN 55447
763-509-1606

Official Contact: Katlin Adamski
Regulatory Affairs Specialist, Cantel

Date: 06 December 2017

Trade Name: **EON Portable Reverse Osmosis Water Purification System**
Common Name: Water Purification System
Regulation Name: Water Purification System for Hemodiaylsis
Product Code: FIP
Device Class: II
Regulation No: 876.5665

Cantel has supplied the following information to the US Food and Drug Administration to support substantial equivalence of EON Portable Reverse Osmosis Water Purification System to its predicate – Millenium HX (MHX) Portable Reverse Osmosis Water Purification System, 510(k) K110578 – currently cleared for sale in the U.S.

1. **Intended Use**

   The EON Portable Reverse Osmosis Water Purification System is intended to be used as a dialysis accessory to produce water through reverse osmosis for use with hemodialysis equipment. EON can be connected to hemodialysis equipment used in hospitals, clinics and in home environments, in conjunction with the appropriate pre and post treatment units, as part of a water treatment system designed to meet current AAMI and Federal (U.S.) standards.

   EON has optional heat disinfection cycles intended to disinfect the reverse osmosis (RO) machine and product loop, and connection tubing to the hemodialysis machine. EON's heat disinfection cycle to disinfect the connection tubing (heat forward cycle) is intended to be used only with hemodialysis machines which contain their own heat disinfection cycles and hence are able to tolerate high temperatures. EON is not intended to heat disinfect the hemodialysis machine.

2. **Device Description**

   The device is a portable water purification system which uses reverse osmosis to remove contaminants from water that is used to dilute dialysis concentrate to form dialysate for use in hemodialysis equipment. Feed water enters the unit and is directed through a pump into a RO membrane. The pump applies a high hydrostatic pressure that forces water from the concentrated (feed) side to the dilute (product) side of the RO membrane. As water flows across the membrane purified water is produced. Both devices are designed to maintain low microbiological levels in the flow pathway by using optional cycles which perform heat disinfection on the entire RO machine and

loop. The subject device also has an optional Heat Forward cycle which is intended to heat disinfect the connection tubing to the hemodialysis machine.

3. Comparison to Other Devices in Commercial Distribution Within the United States

EON is equivalent in intended use, function and fundamental technology to its predicate device, Millenium HX (MHX) Portable Reverse Osmosis Purification System cleared under 510(k) K110578.

Similarities between Subject and Predicate Devices

EON is equivalent in function, intended use, scientific technology, principle of operation, performance characteristics and components to MHX. Both the subject and predicate devices utilize chemical sanitization and heat disinfection of the RO loop and machine.

Differences between Subject and Predicate Devices

The only difference between the devices is that the subject device has an optional Heat Forward cycle which is used to heat disinfect the connection tubing between EON and the hemodialysis machine.

A device comparison table which supports substantial equivalence of the subject device to the predicate device is provided below:

Table 1 – Device Comparison Table

Critical Parameters	Subject Device – EON	Predicate Device – MHX (K110578)
Trade Name	EON Portable Reverse Osmosis Water Purification System	MHX Portable Reverse Osmosis Water Purification System
Regulation Number	876.5665	876.5665
Device Class	Class II	Class II
Certification Panel	Gastroenterology/Urology	Gastroenterology/Urology
Product Code	FIP	FIP
Intended Use	To produce purified water through reverse osmosis for use with hemodialysis equipment.	To produce purified water through reverse osmosis for use with hemodialysis equipment.
Type of Machine Function	Electro-mechanical	Electro-mechanical
Mechanism of Action	Reverse Osmosis	Reverse Osmosis
Heat disinfect RO system	Yes	Yes
Optional heat disinfection of connection tubing	Yes	No
Portable	Yes	Yes
Heater	Inline heater	Tank heater

4. Summary of Non-Clinical Performance Data

Cantel has conducted the following testing to demonstrate that EON is safe and effective for its intended use:

- Performance Testing – performance testing has been conducted on the subject device to ensure it performs with the same safety and effectiveness as the predicate device. The below list briefly discusses the performance testing.
  - Heat Forward Cycle Verification Testing – Demonstrates the ability of the subject device's heat forward cycle to provide water for thermal disinfection to the connection tubing.
  - Heat Disinfection Validation Testing – Demonstrates the effectiveness of the subject device's heat disinfection cycle to reduce microbial contaminants.
- Electrical Safety and Electromagnetic Compatibility – Electrical safety and electromagnetic compatibility testing has been conducted to demonstrate compliance with IEC 61010 and IEC 61326.
- Biocompatibility – Biocompatibility testing has been conducted to demonstrate compliance with ISO 10993-5. The testing was performed to demonstrate that the water contacting materials contained in the subject device are compatible with the intended use of the device and do not release toxic substances into the purified product water.

5. Conclusion

Based on the intended use, fundamental technology and performance data, the subject device is substantially equivalent to and is as safe and as effective as the legally marketed predicate device.