April 16, 2020

Mar Cor Purification, Inc.
Mark Arnold
Regulatory Affairs Manager
14550 28th Avenue North
Minneapolis, MN 55447

Re: K200670
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: March 9, 2020
Received: March 17, 2020

Dear Mark Arnold:

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. 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 located 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.

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) for devices or postmarketing safety reporting (21 CFR 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 4, Subpart A) for combination products; 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 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,

Carolyn Y. Neuland, Ph.D.
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

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*

K200670

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.

March 9, 2020

EON
Portable Reverse Osmosis Water Purification System

Section 07 - 510(k) Summary

Manufacturer: Mar Cor Purification, Inc.

Address: 14550 28th Avenue North
Minneapolis, MN 55447
844-348-5636

Official Contact: Mark Arnold
Regulatory Affairs Manager, Mar Cor Purification, Inc.

Trade Name: **EON Portable Reverse Osmosis Water Purification System**
Common Name: Water Purification System
Classification Name: Water Purification System for Hemodialysis
Product Code: FIP
Device Class: II
Regulation No: 21 CFR 876.5665

Mar Cor Purification has supplied the following information to the US Food and Drug Administration to support substantial equivalence of the EON Portable Reverse Osmosis Water Purification System to its predicates – EON Portable Reverse Osmosis Water Purification System, 510(k) K171099 and WRO 300H, 510(k) K093608 – both currently cleared for sale in the U.S.

1. 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 subject and predicate 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.

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The EON is capable of generating purified water that meets AAMI water quality requirements for hemodialysis. It must be used with appropriate pre and post treatment units, including at a minimum carbon adsorption media pretreatment in order to remove chlorine/chloramines. Additional pre and post treatment requirements may vary and are dependent on the quality of the local feed water supply and individual facility requirements.

The EON system is designed to maintain low microbiological levels in the flow pathway through regular heat disinfection and chemical sanitization. Notable components and features of the EON include:

- RO membrane
- System pump
- Water quality monitoring system
- Operating panel and programmable logic controller (OPLC)
- Heat disinfection and chemical sanitization capability
- Audible and visual alarms
- Automatic divert to drain mode upon start-up and anytime product water TDS is above the quality set-point
- System control via a touch-screen user interface
- Heat forward cycle intended to heat disinfect connection tubing from the Portable Reverse Osmosis Water Purification System to the hemodialysis machine.

2. 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.

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

The EON is equivalent in intended use, functions and fundamental technology to its predicate devices, the Cantel EON Portable Reverse Osmosis Water Purification System (K171099) and Mar Cor (formerly Gambro) WRO 300H (K093608). All three products are portable reverse osmosis water purification systems with the same intended use and equivalent indications for use.

Similarities between Subject and Predicate Devices

EON is equivalent in function, intended use, scientific technology, principle of operation, performance characteristics and components its predicates. 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 subject device is identical in build to the EON Portable Reverse Osmosis Water Purification System (K171099), except it uses the membrane from the WRO 300H (K093608), and has several minor component changes to adjust for dimensional fit.

4. Summary of Non-Clinical Performance Data

Mar Cor Purification has conducted the following testing to demonstrate that the use of the WRO 300H membrane in the EON is safe and effective for its intended use:

- System and RO Membrane Performance – Flow and product water quality verification over range of operating conditions
- Software Verification

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 devices.