July 19, 2023

Evoqua Water Technologies LLC
Robert Dudek
Product Compliance Manager
558 Clark Road
Tewksbury, Massachusetts 01876

Re: K231410
Trade/Device Name: RenaPure Endotoxin Retentive Filter
Regulation Number: 21 CFR 876.5665
Regulation Name: Water purification systems for hemodialysis
Regulatory Class: Class II
Product Code: FIP
Dated: May 1, 2023
Received: May 15, 2023

Dear Robert Dudek:

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,

Gema Gonzalez -S

Gema Gonzalez
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: 06/30/2023
See PRA Statement below.

Submission Number *(if known)*

Device Name

RenaPure Endotoxin Retentive Filter

Indications for Use *(Describe)*

The RenaPure filter is a bacterial and endotoxin retentive filter intended for use in a centralized loop as the final step of a water purification cascade to provide standard dialysis water to machine servicing multiple patients. This filter is not intended to service as the sole means of water purification and therefore must be used in conjunction with other water treatment equipment.

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.

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510(k) Summary: RenaPure® Endotoxin Retentive Filter

Submitter	Evoqua Water Technologies LLC 558 Clark Road Tewksbury MA, 01876 Owner/Operator :10057016
Contact Person	Robert Dudek Manager, Product Compliance robert.dudek@evoqua.com (978) 614-7359
Date Prepared	May 10, 2023
Device Name	RenaPure® Endotoxin Retentive Filter
Trade Name	RenaPure® Filter
Classification Name	Water purification system for hemodialysis, 21 CFR 876.5665
Device Class	Class II
Certification Panel	Gastroenterology/Urology
Product Code	FIP
Predicate Device	Gambro Posiclear Filter – K061782
Device Description	The RenaPure filter is a 20” cartridge style filter in a polypropylene casing that contains dual-layered, 0.22 micron polyethersulfone (PES) pleated membranes which are separated by polypropylene screen layers. The PES membrane is charge modified with a positive charge coating, similar to the predicate device, that aids in removal of endotoxin by charge attraction. Filter configurations are based on an industry standard 222 header design with silicone O-rings at the open end of the filter and flat or fin end caps at the closed end. The filter cartridge is installed in a durable filter housing and operates in a dead-end mode. The filter is designed to remove bacteria and endotoxin from water used in hemodialysis with similar water flow characteristics as the predicate device. The filter provided non-sterile.
Indications for Use	The RenaPure filter is a bacterial and endotoxin retentive filter intended for use in a centralized loop as the final step of a water purification cascade to provide standard dialysis water to machine servicing multiple patients. This filter is not intended to service as the sole means of water purification and therefore must be used in conjunction with other water treatment equipment.
Technological Characteristics	Retention of bacteria by size exclusion (membrane pore size) and retention of endotoxin by charge attraction (charge modified membrane) is achieved in the same way for both the RenaPure filter and the predicate device. Materials of construction are similar to the predicate device, with the exception that a polyethersulfone base membrane is used, this providing better heat stability for hot water disinfection routines performed during use of the device.

Non-clinical Performance Assessment	Performance (bench) testing has been performed which included (a) Flow/Pressure Drop measurements, (b) Endotoxin Retention, (c) Bacterial Retention, (d) Compatibility to Hot Water and Chemical Disinfections, (e) Housing Fit tests, and (f) Compatibility with Deionized water. Testing demonstrated that the RenaPure filter met the intended design requirements and will operate as a drop-in replacement to the predicate device.
Biocompatibility	A series of biocompatibility tests was performed on the RenaPure filter based on it being used as an externally communicating, indirect blood contact device. This testing also included an exhaustive extraction test to identify extractables/leachables from the RenaPure filter followed by a toxicological risk assessment. Additional biocompatibility tests were performed after exposing the RenaPure to simulated hot water disinfection and chemical disinfection routines. All biocompatibility testing passed and the risk of any toxic leachates from the RenaPure filter were considered negligible.
Conclusion	Review of the Indications for Use, the technological characteristic comparison, and the Non-Clinical Performance testing support the substantial equivalence to the predicate device. This determination, along with the biocompatibility testing that was performed, provide evidence that the RenaPure filter is as safe and effective as the predicate device and therefore ready for clinical use.