June 2, 2023

i3 Membrane GmbH
Thor Hinnerk Meyer
Product & Project Manager
Theodorstrasse 41P
Hamburg, 22761
GERMANY

Re: K222727
Trade/Device Name: i3 ONE (203100-S); i3 TWO connect (203200-S);
i3 TWO direct (203300-S)
Regulation Number: 21 CFR 876.5665
Regulation Name: Water purification system for hemodialysis
Regulatory Class: II
Product Code: NHV
Dated: September 5, 2022
Received: May 5, 2023

Dear Thor Hinnerk Meyer:

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, MS
Acting 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)*

K222727

Device Name

i3 ONE (203100-S);
i3 TWO connect (203200-S);
i3 TWO direct (203300-S)

Indications for Use *(Describe)*

The intended use of the i3 Membrane Water Filters i3 ONE, i3 TWO connect, i3 TWO direct is to filter EPA quality drinking water. The i3 Membrane Water Filters retain bacteria, which may aid in infection control. The filters produce water that is appropriate for washing and drinking, superficial wound cleansing (minor cuts, scrapes and abrasions), cleaning of equipment used in medical procedures and washing of surgeon's hands. The i3 Membrane Water Filters are not intended to provide water that can be used as a substitute for USP grade sterile water.

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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Section 5: 510(k) Summary

As required by 21 CFR 807.92

Submitter Information

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Device Identification

Trade Name:	i3 ONE / i3 TWO connect / i3 TWO direct
Common Name:	Point-of-Use Water Filter
Classification Name:	Water purification system for hemodialysis
Classification Product Code:	NHV
Panel:	Gastroenterology/Urology
Predicate Device: Reference Device:	Pall-Aquasafe Water Filter, K153434 Ecolab POU Water Filter, K182164

Device Description / Intended Use

The i3 Point-of-Use Water Filters are supplied sterile and 100% integrity tested. The membrane within the filter cartridge is rated and validated at 0.2 µm to remove bacteria and particles in the water supply. This membrane reduces bacteria with more than 7 log levels per square centimeter filtration area. This represents the bacterial retention, the core element of infection prevention.
Furthermore, a bacteriostatic additive is present in the outer housings parts of the filter, which prevents retrograde contamination of the filter.
In addition, the inlet of the tap water filter is inclined to prevent the water from hitting the siphon. This also prevents retrograde contamination from the siphon, which would be caused by rising aerosols from the direct impact of the water jet.
The Water Filters are designed to be used for a maximum of 50 days following initial connection. Suspending use does not extend filter life. The i3 ONE / i3 TWO connect / i3 TWO direct Water Filters are intended to be used within the healthcare environment such as hospitals, nursing homes, health care facilities or clinical settings where immune-compromised patients may be exposed to waterborne microorganisms originating from the water supply.

The i3 Membrane Water Filters are disposable and designed for the use on tap or the shower.

Indications for Use

The intended use of the i3 Membrane Water Filters i3 ONE, i3 TWO connect, i3 TWO direct is to filter EPA quality drinking water. The i3 Membrane Water Filters retain bacteria, which may aid in infection control. The filters produce water that is appropriate for washing and drinking, superficial wound cleansing (minor cuts, scrapes and abrasions), cleaning of equipment used in medical procedures and washing of surgeon's hands. The i3 Membrane Water Filters are not intended to provide water that can be used as a substitute for USP grade sterile water.

Performance Data

Non-clinical performance testing was conducted to characterize the subject i3 Water Filters and is summarized as follows:

- **Microbial Retention**

The examinations for bacterial retention of the i3 Membrane Water Filters following ASTM F 838 - 15a: *Standard Test Method for Determining Bacterial Retention of Membrane Filters Utilized for Liquid Filtration* showed very good retention performances of the tested filter with reductions of the bacterial count of more than 10^7 colony-forming units (CFU)/cm^2 filter area. All filters passed the filter integrity test prior to and after the performance of the bacterial retention test.

- **Evaluation of Bacteriostatic Additive**

The effect of antibacterial activity on plastic surface has been proven. The bacteriostatic additive reduces a retrograde contamination of the filters by more than 99.5% for *Pseudomonas aeruginosa* even after 8 weeks of use. Further tests were carried out with *Escherichia coli*, *Klebsellia pneumoniae, Proteus mirabilis, Acinetobacter baumannii* and *Staphylococcus aureus*. Here the protection against retrograde contamination was also 99.5% in each case.

- **Silver Migration Testing**

The Material of the filter was analyzed on its silver content and the migration of silver ions in water was simulated. The measurements of any silver-based ions were done using optical emission spectrometry (ICP-OES). The silver-based ions were found to be more than 10 times less according to the suggestion of the Environmental Protection Agency.

- **Maximum Operating Temperature and Pressure Testing**

All i3 Membrane Water Filters were tested at up to 5 bar and up to 70°C (for a continuous period of 30 minutes) to ensure that filters withstand a thermal disinfection. Filters were integrity tested after these tests to verify that these conditions are withstood.

- **Flow Rate Testing**

All filters were tested at 1, 2, 3, 4 and 5 bar (approx. 15, 30, 45, 60 and 75 PSI) static water pressure for the respective flow. The intended use of the filters can be guaranteed at each of these pressures.

- **Sterilization Testing**

The i3 Membrane Water Filters are available sterile with a shelf life of 50 days. Bioburden and sterilization validation were assessed and conducted. The microbiological validation has been successful and the sterilization dose of 25 kGy for SAL 10^{-6} has been substantiated.

- **Shelf Life Testing**

The shelf life of i3 Membrane Water Filters has been tested by a 5-year accelerated test and a 5-year real time ageing test is started in 2019. The packaging was then subject to a peel test, a dye test and a bubble test. All tests were passed. The filter is therefore sterile even after a 5-year life and can be used safely during this period. Further integrity tests of the filter have been carried out.

- **Biocompatibility Testing**

A biocompatibility review for all three i3 Membrane Water Filters for which a 510(k) clearance is requested was performed. The biocompatibility was performed using the ISO 10993-1 standard and subsequent ISO 10993 series standards and concluded that the products are biocompatible.

- **Additional Tests**

During verification the following tests were performed and successfully passed according to the product specifications:

- Burst Pressure Testing
- Durability Testing
- Transport Testing
- Drop Testing
- Chlorine Testing for chemical disinfection
- Wipe Disinfection Testing

Risk Management

Hazards associated with design and development, verification and validation, and all manufacturing and sterilization processes, and use of the i3 Membrane POU Water Filters have been assessed under ISO 14971 and documented in the risk management file and related documents. The full product life cycle is also considered in the risk management plan. The results of the residual risk assessment conclude that no additional actions are necessary with risk reduction and control actives having been completed.

No risk was deemed unacceptable, and the overall risk profile of the device was deemed to be low as all risks are mitigated under design control and ASTM testing.

Substantial Equivalence Discussion

This Premarket Notification Submission requests clearance for the i3 ONE / i3 TWO connect / i3 TWO direct Water Filters. A comparison of the i3 ONE / i3 TWO connect / i3 TWO direct Water Filters to the predicate devices is provided in the following table.

	Subject Device	**Primary Predicate**	**Reference Device**
510(k) Number	N/A	K153434	K182164
Trade Name	i3 Point-of-Use Water Filter Filter Models: i3 ONE, i3 TWO connect, i3 TWO direct	Pall-Aquasafe™Water Filter Models: AQINA, AQ31F1SA, AQ31F1RA, AQF4A	Ecolab POU Water Filter
Manufacturer	i3 Membrane GmbH	Pall Medical	Ecolab Inc.
Indications for Use	The intended use of the i3 Membrane Water Filters i3 ONE, i3 TWO connect, i3 TWO direct is to filter EPA quality drinking water. The i3 Membrane Water Filters retain bacteria, which may aid in infection control. The filters produce water that is appropriate for washing and drinking, superficial wound cleansing (minor cuts, scrapes and abrasions), cleaning of equipment used in medical procedures and washing of surgeon's hands. The i3 Membrane Water Filters are not intended to provide water that can be	The Pall-Aquasafe™Water Filter is intended to be used to filter EPA (Environmental Protection Agency in USA) quality drinking water. By retaining bacteria, the filters may aid in infection control. The filters produce water that is suitable for washing and drinking, superficial wound cleansing (minor cuts, scrapes, or abrasions), cleaning of equipment used in medical procedures and washing of surgeon's hands. The filters are not intended to provide water that can be used as a substitute for USP grade sterile water.	The Ecolab POU Water Filters are intended to operate on EPA quality drinking water sources as a microbial retention filter. Ecolab POU Water Filters are suitable for the control of bacteria equal to or greater in size than Brevundimons diminuta. The POU Filters are suitable for general point of use infection control for procedures such as superficial wound cleansing, cleaning of equipment, washing of surgeon's hands

	used as a substitute for USP grade sterile water.		and bathing where the reduction of such microorganisms in the water is desired. The Ecolab POU Filters are not intended for use in the production of USP sterile water for use in infusion, injection or production of fluids for use in dialysis treatments.
Device Description	A disposable Polyethersulfone (PES) membrane filter sealed in a polypropylene housing designed to be installed at point of use locations where the control of bacteria in EPA quality drinking water is desired for hand-washing, bathing, showering and instrument cleaning applications. These filters are designed to be installed as attachments to faucets or as a handheld shower head attached to a water outlet.	Sterilizing grade 0.2 µm Supor® membrane filtration with integral pre-filter that retains bacteria from water through size exclusion.	A disposable Polyethersulfone (PES) membrane filter sealed in a white polypropylene housing designed to be installed by facility personnel at point of use locations where the control of bacteria in EPA quality drinking water is desired for hand-washing, bathing, showering and instrument cleaning applications. These filters are designed to be installed as attachments to faucets or as a handheld shower head attached to a water outlet.
Materials			
Casing	Polpropylene (PP)	Polybutylene terephthalate (PBT)	Polypropylene (PP)

Filter Elements	0,2 µm Polyethersulfone (PES) pleated membrane	0.2 µm Supor®(Polyethersulfone) membrane filtration with integral pre-filter	Polyethersulfone (PES)pleated membrane
Operation			
Feed Water Source	Drinking water plumbing at Point of Use	In-line plumbing	Drinking water plumbing at point of use.
Use Life	50 days	31 days	Up to 62 days
Maximum Inlet Pressure	75 psi @ 140 °F	75 psi @ 140 °F	89.9 psi (6.2 bargauge): tapfilters 79.8 psi (5.5 bargauge): showerwands
Flow Rate and Pressure Drop	Per individual model specification	Per individual model specification	7L/min and 11L/min at 3 bar
Filter Retention			
Bacteria Reduction	> 10^7 CFU/cm^2 > 10^{10} CFU/device	> 10^7 CFU/cm^2 > 10^{10} CFU/device	Greater than 10^7

Table 1: Comparison with Predicate and Reference Device

Substantial Equivalence

Comparison of the indications for use, technical characteristics and performance of the i3 Membrane Water Filters and the Pall-Aquasafe Water Filter provided in the 510(k) submission, is sufficient to demonstrate substantial equivalence. All test performance of non-clinical tests is at least as safe as the predicate device test results. If they are used after the intended use, no new questions about safety or effectiveness arise. It is at least as safe and effective as previous legally marketed devices.