June 14, 2023

Bellco S.r.l.
% Michele Gust
VP, Regulatory and Quality
Mozarc Medical
710 Medtronic Parkway (LT140)
Minneapolis, Minnesota 55432

Re: K231406
Trade/Device Name: Clearum™ HS 17
Regulation Number: 21 CFR 876.5860
Regulation Name: High permeability hemodialysis system
Regulatory Class: II
Product Code: KDI
Dated: May 15, 2023
Received: May 15, 2023

Dear Michele Gust:

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.

510(k) Number *(if known)*
K231406

Device Name
Clearum™ HS 17

Indications for Use *(Describe)*
The Clearum™ HS 17 is intended for use in acute or chronic renal failure patients requiring hemodialysis

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

SUBMITTER: Bellco S.r.l.
Via Camurana, 1
41037 Mirandola (MO) Italy

CONTACT PERSON: Michele Gust
Telephone: 763-505-4016
E-mail: michele.gust@medtronic.com

DATE PREPARED: May 11, 2023

DEVICE TRADE NAME: Clearum™ HS 17

COMMON NAMES: Hollow fiber dialyzers

CLASSIFICATION NAME: High permeability hemodialysis system

PREDICATE DEVICES: Clearum™ HS 17 (K193542)

DEVICE DESCRIPTION:

The Clearum™ HS 17 dialyzer is consisting of a cylindrical polypropylene body containing a bundle of microporous hollow fibers made of polyethersulfone (PES) secured to the ends by means of hot-melt polyurethane resin.

The modifed Clearum™ HS 17 dialyzer is substantially equivalent to the predicate Clearum™ HS 17 dialyzer manufactured by Bellco (K193542, cleared on October 8, 2020).

The device is characterized by a membrane surface area equivalent to 1.7 m^2, and by an outer housing total height of 306 mm and a maximum outside diameter of 44 mm.

Identical to the predicate Clearum™ HS 17, blood and dialysate flow in a countercurrent in their respective compartments. In this process, toxins and fluid are transferred across the semipermeable membrane from the blood to the dialysate compartment.

The dialyzers are sterilized using moist heat with saturated steam, have a non-pyrogenic fluid path, and are labeled for single use.

INDICATION FOR USE:

The Clearum™ HS 17 is intended for use in acute or chronic renal failure patients requiring hemodialysis.

TECHNOLOGICAL CHARACTERISTICS:

The modified Clearum™ HS 17 has the same fundamental technological characteristics, principles of operation and control mechanisms as the predicate device.

As compared to the predicate device, the modified Clearum™ HS 17 is characterized by a different fiber undulation amplitude that has been increased from 0.5 to 0.6 millimeters. As a consequence, the effective fiber length also increases from 246 to 247 millimeters.

The design has not been changed. No modification described in the present 510(k) applies to other device components except for the fiber.

No change to the intended use has been made as a result of the modifications.

The modified and the predicate Clearum™ HS 17 devices share the same fundamental technological characteristics and the same device function.
The increased fiber undulation amplitude does not raise any new issues of safety and effectiveness.

The modified device is substantially equivalent to the predicate device with respect to intended use, function, sterilization method, operating principles, control mechanisms, manufacturing process and fundamental scientific technology.

There are no differences in packaging type and material between predicate and modified device.

The Clearum™ HS 17 is sterilized using moist heat with saturated steam and have a non-pyrogenic fluid path. The device is for single use only.

The table below compares the modified Clearum™ HS 17 to the predicate Clearum™ HS 17.

Comparison of Modified Clearum™ HS 17 vs. Predicate Clearum™ HS 17

Parameters	Clearum™ HS 17 Predicate device (K193542)	Clearum™ HS 17 Modified device
Intended use	The Clearum™ HS 17 is intended for use in acute or chronic renal failure patients requiring hemodialysis	Same
Fiber Chemical Composition	Clearum GmbH Polyethersulfone (PES), Polyvinyl-pryrrolidone (PVP)	Same
Potting Resin for Fibers	Polyurethane	Same
Dialysate port caps	Polypropylene	Same
Blood port caps	Polypropylene	Same
Headers	Polypropylene	Same
O-rings	Silicone Rubber	Same
Housing	Polypropylene	Same
Fiber Internal Diameter (measured average)	200 µm	Same
Fiber undulation amplitude (mm)	0.5	0.6
Fiber undulation wavelength (mm)	0.8	Same
Wall Thickness	40 µm	Same
Number of fibers	11150	Same
Effective fiber length (mm)	246	247
Outer housing Height (mm)	306	Same
Maximum outside diameter (mm)	55	Same
Minimum inside diameter (mm)	39.40	Same
Priming Volume (ml)	105	Same
Blood Connector	luer-type	Same
Dialysate Connector	Hansen-type	Same
Casing geometry	Cylindrical body	Same
Packaging type	Single/Multi unit box	Same
Packaging material	Plastic pouch/carton box	Same
Shelf life	3 Years	6 months
Method of Sterilization	Moist heat with saturated steam	Same
Manufacturer	Bellco S.r.l.	Same

NON CLINICAL TEST RESULTS

The raw materials have not been modified as a result of this change. The modified Clearum™ HS 17 is manufactured with the same biocompatible materials as the predicate device. Also, the manufacturing flow is fully identical. The processing of the materials, manufacturing methods and steps have not been changed.
The are no new or increased biocompatibility concerns as there is no change to the raw materials nor the processing agents/steps that the fiber is subjected to; therefore, biocompatibility testing was not repeated. The biocompatibility testing and/or chemical characterization followed by a toxicological risk assessment that was completed on the predicate Clearum™ HS 17 applies to the modified Clearum™ HS 17 in accordance with the requirements of ISO 10993-1 and the guidelines of the Guidance “Use of International Standard ISO-10993, "Biological Evaluation of Medical Devices Part 1: Evaluation and Testing”.

IN-VITRO TEST RESULTS

In vitro testing was conducted on both the modified and predicate Clearum™ HS 17 for comparative purpose. The test results demonstrated the substantial equivalence.
Testing was conducted in accordance with the relevant requirements of “Guidance for the Content of Premarket Notifications for Conventional and High Permeability Hemodialyzers, issued on August 7, 1998” as well as the related ISO 8637-1:2017 – “Cardiovascular implants and extracorporeal systems - Hemodialysers, hemodiafilters, hemofilters and hemoconcentrators”.
Device performance testing included:

- Priming Volume
- Pressure Drop across Blood Compartment (Resistance to Flow)
- Pressure Drop across Dialysate Compartment (Resistance to Flow)
- Ultrafiltration Coefficient
- Sieving Coefficient: Albumin, Myoglobin, Inulin
- Clearance: Urea, Creatinine, Phosphate, and Vitamin B12
- Hemo-compatibility (mechanical hemolysis)

The results of the testing met the performance specifications demonstrating that the modified Clearum™ HS 17 performs as intended. The predicate device substantial equivalence was also demonstrated.

CONCLUSIONS

The results on in vitro studies demonstrate the modified Clearum™ HS 17 performs as per design specifications and is equivalent to the predicate device with respect to device function. Additional testing has also demonstrated the effectiveness of production techniques to assure that the device is sterile and non-pyrogenic.