October 8, 2020

Bellco Srl
% Michele Gust
Sr. Regulatory Affairs Director, Renal Care Solutions
Medtronic, Inc.
710 Medtronic Parkway (LT140)
Minneapolis, MN 55432

Re: K193542
Trade/Device Name: Clearum HS Family
Clearum HS Models: HS 13, HS 15, HS 17, HS 20, HS 22
Regulation Number: 21 CFR 876.5860
Regulation Name: High permeability hemodialysis system
Regulatory Class: II
Product Code: KDI
Dated: September 4, 2020
Received: September 8, 2020

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,

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)*

K193542

Device Name
Clearum™ HS Family

Clearum™ HS Models: HS 13, HS 15, HS 17, HS 20, HS 22

Indications for Use *(Describe)*
The Clearum™ HS dialyzer family 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.

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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
DATE PREPARED:	Aug 14, 2020
TRADE NAMES:	Clearum™ HS family Clearum™ HS Models**:** HS 13, HS 15, HS 17, HS 20, HS 22
COMMON NAMES:	Hollow fiber dialyzers
REGULATION and CLASS:	21 CFR §876.5860, Class II
PRODUCT CODE:	KDI
CLASSIFICATION PANEL:	Gastroenterology / Urology (78)
CLASSIFICATION NAMES:	High permeability hemodialysis system
PREDICATE DEVICES:	Polyflux H models: 140H, 170H, 210H (K030592, cleared on May 23 2003, manufactured by Gambro now Baxter Healthcare Corporation)

5.1. Device Description

The Clearum™ HS family consists of dialyzers comprised by 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 Clearum™ HS dialyzers are substantially equivalent to Polyflux H models manufactured by Gambro now Baxter Healthcare Corporation (K030592, cleared on May 23, 2003).

The devices are available in different models which differentiate by membrane surface area, ranging from 1.3 to 2.2 m^2, and for the dimensions of the outer cylindrical body in terms of length and height (306 x 41 mm for the surface areas in the range 1.3-1.5 m^2, 306 x 44 mm for the surface area 1.7 m^2 and 366 x 44 mm for the surface areas in the range 2.0-2.2 m^2).

Similar to other commercially available hemodialyzers, 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.

5.2. Indication for Use

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

5.3. Technological Characteristics

The main design features, operating principle and basic function of the Clearum™ HS dialyzers are substantially equivalent to the predicate device, Polyflux H dialyzers family.

Both the test and predicate devices have a cylindrical housing containing a bundle of microporous hollow fiber membranes.

For both devices, blood and dialysate flow in a countercurrent in their respective compartments, thus resulting in the transfer of toxins and fluid across the semipermeable membrane from the blood to the dialysate compartment.

The table below compares the Clearum™ HS family to the predicate device for all the available information that have been retrieved from labeling information and from the FOI

Service Inc. For clarity an indication “not av.” has been added when an information was not available for the competitor’s devices.

Table 5-1: Comparison Clearum™ HS Dialyzers Family vs. PolyFlux H Dialyzers Family

Parameter	Clearum™ HS Dialyzer Family	PolyFlux H Dialyzer Family Predicate device (K030592)
Intended Use	The Clearum™ HS dialyzer family is intended for use in acute or chronic renal failure patients requiring hemodialysis.	The capillary dialyzer/filter is intended for use in Hemodialysis, Hemodiafiltration, Hemofiltration for the treatment of chronic or acute renal failure.
Potting Resin for Fibers	Polyurethane	Polyurethane
Dialysate port caps	Polypropylene	Polypropylene
Blood port caps	Polypropylene	Polypropylene
Headers	Polypropylene	Polycarbonate
O-rings	Silicone Rubber	Silicone Rubber
Housing	Polypropylene	Polycarbonate
Fiber Chemical Composition	Clearum GmbH Polyethersulfone (PES), Polyvinyl-pyrrolidone (PVP)	Polyamix™ Polyarylethersulfone (PAES), Polyvinyl-pyrrolidone (PVP)
Fiber Internal Diameter (measured average) (µm)	200 (for all the models)	215

Parameter	Clearum™ HS Dialyzer Family	PolyFlux H Dialyzer Family Predicate device (K030592)
Wall Thickness (µm)	40 (for all the models)	50
Number of fibers	HS 13: 8600 HS 15: 9900 HS 17: 11150 HS 20: 10400 HS 22: 11200	Polyflux 140H: 7500 Polyflux 170H: 9300 Polyflux 210H: 12000
Effective fiber length (mm)	HS 13: 246 HS 15: 246 HS 17: 246 HS 20: 308 HS 22: 308	Polyflux 140H: 270 Polyflux 170H: 270 Polyflux 210H: 270
Effective membrane surface area (m2)	HS 13: 1.3 HS 15: 1.5 HS 17: 1.7 HS 20: 2.0 HS 22: 2.2	Polyflux 140H: 1.4 Polyflux 170H: 1.7 Polyflux 210H: 2.1
Configuration: Outer housing Height (mm)	HS 13: 306 HS 15: 306 HS 17: 306 HS 20: 366 HS 22: 366	Not av.
Configuration: Maximum outside diameter (mm)	55 (for all the models)	Not av.

Parameter	Clearum™ HS Dialyzer Family	PolyFlux H Dialyzer Family Predicate device (K030592)
Configuration: Minimum inside diameter (mm)	HS 13: 36.75 HS 15: 36.75 HS 17: 39.40 HS 20: 39.40 HS 22: 39.40	Not av.
Configuration: overall casing geometry	Cylindrical body	Cylindrical body
Priming volume (ml)	HS 13: 84 HS 15: 95 HS 17: 105 HS 20: 120 HS 22: 126	Polyflux 140H: 94 Polyflux 170H: 115 Polyflux 210H: 125
Sterilization method	Moist heat with saturated steam	Moist heat with saturated steam

5.4. Non-Clinical Test Results

Applicable tests were conducted in accordance with the requirements of ISO 10993-1.

The Guidance “Use of International Standard ISO-10993, "Biological Evaluation of Medical Devices Part 1: Evaluation and Testing” and its guidelines was also considered limited to external communicating device, circulating blood, prolonged contact duration.

5.5. In-Vitro Test Results

In vitro testing was conducted on the entire Clearum™ HS dialyzers family. The tests performed demonstrate the predicate device 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)

For comparative purposes, the same testing, was also conducted on the Polyflux H predicate device, when applicable.

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

5.6. Conclusions

The results on in vitro studies demonstrate the Clearum™ HS dialyzers perform as per design specifications and are 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.