July 23, 2021

Haemopharm Biofluids S.r.l.
Francesca Curti
Regulatory Affairs Specialist
Via dell'Industria 6
Tovo di S. Agata, Sondrio 23030
ITALY

Re: K212052
Trade/Device Name: HMB32 Dialysis Solution
Regulation Number: 21 CFR 876.5820
Regulation Name: Hemodialysis system and accessories
Regulatory Class: II
Product Code: KPO
Dated: June 25, 2021
Received: June 30, 2021

Dear Francesca Curti:

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,

for 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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*

K212052

Device Name
HMB32 Dialysis solution

Indications for Use *(Describe)*
Intended for use as a dialysis solution in Continuous Renal Replacement Therapy.

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.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

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"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

510(k) Summary

Date Prepared: July 22, 2021

Submitter: Haemopharm Biofluids S.r.l.
Via dell'Industria 6
23030 Tovo S. Agata
Sondrio, Italy
Establish Registration Number: 3010242164

Contact Person: Francesca Curti
Regulatory Affairs Specialist
Phone: +39 0342 77 1019
Email: francesca.curti@medtronic.com

Device Name and Classification:

Trade Name:	HBiofluids HMB32
Common Name:	Dialysis Solution
Regulation Number:	21 CFR 876.5820
Product Code:	KPO
Classification:	Class II

Predicate Device

Haemofiltration and Dialysis Solutions (K150966)

Device Description

The HBiofluids HMB32 is a bicarbonate-based dialysis solution packaged in a ready to mix, sterile, non-pyrogenic, two-chambered solution container system. One chamber contains the acidic solution and one chamber contains the basic solution. At the point of use, the membrane between the two chambers is opened, and the acidic and basic solutions are mixed to form the final ionic composition of the solution to be used in the Continuous Renal Replacement Therapy (CRRT) treatment. This solution is delivered to the patient while undergoing CRRT treatment in a healthcare facility.

The HBiofluids HMB32 solution will be offered in one formulation, in two different volumes: 500 mL +4500mL and 500mL +1500mL.

Models	Description
MD042	HBiofluids HMB32 Dialysis solution, 500mL+1500mL
MD088	HBiofluids HMB32 Dialysis solution, 500+4500 mL

The chemical compositions of the final solutions for these two volumes are shown in the table below.

Ions	Concentration
Na^+	140.00
K^+	2.50
Ca^{++}	1.50
Mg^{++}	0.75
HCO_3^-	32.00
Cl^-	115.00
Glucose	5.55
Theoretical osmolarity	297 mOsm/L

Indications for Use

Intended for use as a dialysis solution in Continuous Renal Replacement Therapy.

Comparison to Predicate Devices

The HMB32 Dialysis Solution has the same intended use, design, and principles of operation and technology when compared to the predicate HMB32 Dialysis Solution.

- Intended Use: The intended use is the same as the predicate device.
- Design: The design is the same as the predicate device.
- Materials: The materials are substantially equivalent to the predicate device.
- Principles of Operation and Technology: The principles of operation are the same as the predicate device.
- Performance: The performance of the device is the same as the predicate device.

Summary of Performance Data

Bench testing was used to demonstrate the performance characteristics of the HBiofluids HMB32 Dialysis solution remain the same. The following testing was performed:

- Bag integrity testing
- Composition testing
- Biocompatibility testing

Clinical testing was not required to establish substantial equivalence.

Conclusion

HBiofluids has demonstrated that the HMB32 Dialysis Solution is substantially equivalent to the predicate device based upon design, test results, and indications for use.