



Food and Drug Administration  
10903 New Hampshire Avenue  
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Silver Spring, MD 20993-0002

December 4, 2015

Haemopharm Biofluids Srl (HBiofluids)  
% Sheila Hemeon-Heyer  
President  
Heyer Regulatory Solutions, LLC  
P.O. Box 2151  
Amherst, MA 01004-2151

Re: K150966  
Trade/Device Name: HMB32 500 + 4500 ml and 500 + 1500 ml  
Regulation Number: 21 CFR§ 876.5820  
Regulation Name: Hemodialysis system and accessories  
Regulatory Class: II  
Product Code: KPO  
Dated: October 29, 2015  
Received: October 29, 2015

Dear Sheila Hemeon-Heyer,

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. 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); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to <http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm> for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address <http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,

  
**Benjamin R. Fisher -S**

Benjamin R. Fisher, Ph.D.  
Director  
Division of Reproductive, Gastro-Renal,  
and Urological Devices  
Office of Device Evaluation  
Center for Devices and Radiological Health

Enclosure

## Indications for Use

510(k) Number (if known)

K150966

Device Name

HMB32 500 + 4500 ml and 500 + 1500 ml

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.

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**510(k) SUMMARY**

- 1. SUBMITTER:** Haemopharm Biofluids srl  
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Sondrio, Italy
- 2. CONTACT PERSON:** Giuseppe Tomasini  
Phone: 011 39 0535 29323  
Mobile: 011 39 3355733390  
Fax: 011 39 0535 29177
- 3. DATE PREPARED:** April 10, 2015
- 4. DEVICE TRADE NAME:** HMB32  
**MODEL NUMBERS:** (500 + 4500 ml) and (500 + 1500 ml)
- 5. COMMON NAME:** Haemofiltration and Dialysis Solution  
**CLASSIFICATION NAME:** Dialysate Concentrate for Hemodialysis  
(Liquid or Powder)
- 6. CLASSIFICATION:** 21 CFR 876.5820, Product Code KPO  
Class II
- 7. PREDICATE DEVICE(S):** K041428, Accusol Dialysis Solutions, Baxter  
Healthcare

**8. 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 broken, 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.

The HBiofluids HMB32 solution will be offered in one formulation, in two different volumes: 500+4500 ml and 500+1500 ml. The chemical compositions of the final solutions for these two volumes are shown in the substantial equivalence table below.

**9. INDICATION FOR USE:**

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

**10. COMPARISON TO PREDICATE DEVICE:**

The table below provides a technical comparison to the predicate device. There are no significant differences between the HBiofluids HMB32 solution as compared to the predicate Accusol solution.

<b>Parameter</b>	<b>Predicate Device ACCUSOL, K041428</b>	<b>HMB32</b>
<b>Indication for use</b>	For use as a dialysis solution in continuous renal replacement therapy	For use as a dialysis solution in continuous renal replacement therapy
<b>Overall design</b>	The solution is supplied in a carton box containing two units of 5 liter double chamber non-PVC bags.  Each bag is over-wrapped in its overpouch.  The solution in the bag is clear and colorless.	The solution is supplied in a carton box containing two units of 5 liter or four units of 2 liter double chamber PVC free bags.  Each bag is over-wrapped in its overpouch.  The solution in the bag is clear and colorless.
<b>Ionic composition of final solution (mmol/l):</b>  <b>Na<sup>+</sup></b> <b>K<sup>+</sup></b> <b>Ca<sup>++</sup></b> <b>Mg<sup>++</sup></b> <b>HCO<sub>3</sub><sup>-</sup></b> <b>Cl<sup>-</sup></b> <b>Glucose</b> <b>Theoretical osmolarity</b>	140.00 2.00 1.75 0.50 35.00 111.30 5.55 296 mOsm/l	140.00 2.50 1.50 0.75 32.00 115.00 5.55 297 mOsm/l
<b>Solution container components and materials</b>	Supplied in a two chamber container system. At the time of use, the contents of the two chambers are mixed together creating the	Supplied in a two chamber container system. At the time of use, the contents of the two chambers are mixed together creating

Parameter	Predicate Device ACCUSOL, K041428	HMB32
	dialysate solution. The mixed solution is delivered to the dialysate pathway of the blood tubing path through the administration site consisting of a membrane tube and a pull-ring closure and connected to the bottom chamber. A medication port is provided for optional insertion of other substances into the mixed solution prior to use.	the dialysate solution. The mixed solution is delivered to the dialysate pathway of the blood tubing path through the administration tube connected to the bottom chamber, which is opened and closed using a luer lock. A second tube in the large chamber can be used for optional insertion of other substances into the mixed solution prior to use.
<b>Biocompatibility of patient contacting container/closure components</b>	Established via testing per ISO 10993-1	Established via testing per ISO 10993-1
<b>Sterilization</b>	moist heat	moist heat
<b>Shelf life</b>	12 months	12 months

## 11. NONCLINICAL TESTING:

**Biocompatibility:** The HMB32 solution consists of components found in human plasma and is in compliance with the European Pharmacopeia 8.0, "Haemofiltration and haemodiafiltration, solution for," current edition 07/2013:0861. The materials of the container/closure system come into contact with the solution, but do not come into direct contact with the patient. Biological assessments are provided to demonstrate that the materials in contact with the solution are medical grade, meet ISO 10993-1 and USP Class VI plastics requirements, and are commonly used for medical devices and injectable pharmaceuticals.

**Sterilization Validation:** The steam sterilization method was validated to an SAL of  $10^{-6}$  in accordance with EN ISO 17665-1: 2007 Sterilization of health care products – Moist heat – Part 1: Requirements for the development, validation and routine control of sterilization process for medical devices.

**Pyrogenicity** testing conducted using the LAL test confirmed that the solution is not pyrogenic.

Stability testing conducted after real-time aging out to 18 months confirmed the integrity of both the solution and the container/closure system. The HMB32 product will be labeled with a 12 month shelf life.

## **12. CONCLUSION:**

The information and testing presented in this 510(k) demonstrates that the HBiofluids HMB32 is safe and effective for use during Continuous Renal Replacement Therapy as demonstrated by confirmation of substantial equivalence to the Accusol dialysis solution cleared under K041428.