February 1, 2019

Eurotrol B.V.
Mylene de Boer
QA/RA Officer
Keplerlaan 20
Ede, Gelderland, 6716BS, NL

Re: K182744
Trade/Device Name: HemoTrol WB - Low, HemoTrol WB - Normal and HemoTrol WB - High
Regulation Number: 21 CFR 864.8625
Regulation Name: Hematology quality control mixture
Regulatory Class: Class II
Product Code: GGM
Dated: September 26, 2018
Received: September 28, 2018

Dear Mylene de Boer:

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 and Part 809); 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/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Leonthena R. Carrington -S

Lea Carrington
Director
Division of Immunology
and Hematology Devices
Office of In Vitro Diagnostics
and Radiological Health
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)*
K182744

Device Name
HemoTrol® WB - Low, HemoTrol® WB - Normal and HemoTrol® WB - High

Indications for Use *(Describe)*
HemoTrol® WB is an assayed quality control material for professional use to verify the performance characteristics of the HemoCue ® Hb 301 and the HemoCue ® Hb 801 System. HemoTrol® WB is intended for the quantitative determination of hemoglobin.

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

HemoTrol WB

September 2018

This summary of the 510(k) safety and effectiveness information is submitted in accordance with the requirements of 21 CFR 807.92.

Submitter

Eurotrol B.V.

Keplerlaan 20

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T: +31 318 695777

Primary Contact: Ms. Mylène de Boer, mdeboer@eurotrol.com

Device Information

Device name	REF	Classification
HemoTrol ® WB – Low	08718734960942	Class II (21 CFR 864.8625) GGM – control, Hemoglobin
HemoTrol ® WB – Normal	08718734960959	
HemoTrol ® WB – High	08718734960966	

Predicate Device

Eurotrol HemoTrol

510(k) number: K964052

Device Description

HemoTrol® WB is an assayed hemoglobin quality control material intended for professional use in the verification of the precision and accuracy of the HemoCue® 301 and HemoCue® 801 systems. HemoTrol® WB contains bovine red blood cells with hemoglobin lysates in MetHb and additional stabilizers. For daily quality control, three physiological relevant levels are available.

HemoTrol® WB solutions are filled in reclosable plastic primary containers. Each bottle contains 1.1 g of HemoTrol® WB solution. The primary containers are equipped with colored polypropylene caps. Cap color depends on the concentration of hemoglobin (Low: red cap; Normal: white cap; High: blue cap). Two (2) bottles of the same level are placed in a plastic blister and packed in a product box together with the combined instructions for use (IFU) and value sheet. Both the primary containers and product box are labeled.

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Intended Use

New Device

HemoTrol® WB is an assayed quality control material for professional use to verify the performance characteristics of the HemoCue ® Hb 301 and the HemoCue ® Hb 801 System. HemoTrol® WB is intended for the quantitative determination of hemoglobin.

Predicate Device

Eurotrol HemoTrol is an assayed hemoglobin control intended for professional use in the verification of the precision and accuracy of the HemoCue® B-Hemoglobin and the HemoCue Hb 201 systems.

The indication for use for HemoTrol® WB is not identical to the predicate device; however, the differences do not alter the intended diagnostic use of the device, nor do they affect the safety or effectiveness of the device compared to the predicate device. Both Hemotrol® WB and the predicate device are assayed quality control materials for professional use to verify the performance characteristics of a hemoglobin analyzer but are designed for a different hemoglobin analyzer.

Predicate Device Comparison

Parameter	Similarities	Differences
Analyte	Hemoglobin	None
Analyte Concentration	Both devices cover the range of 95-160 g/L	Predicate device also includes: 80-94 g/L
Color of liquid	Bloodlike	None
Contents	Purified bovine hemolisate and preservatives.	Predicate device does not contain stabilized red blood cells
Filling volume	1 ml	None
Intended Use	Quality Control material for professional use to verify the performance characteristics of a specific Hemoglobin analyzer.	Different target Hemoglobin analyzer
Number of Levels	3 levels: Low, Normal, High	None
Open vail stability	31 days	None
Primary Container	Reclosable plastic primary containers with polypropylene caps	None
Principle of Operations	The absorbance is measured by using a dual wavelength spectrophotometric technology.	Measurements are performed at 506 nm and 880 nm. Predicate device at 570 nm and 880 nm.
Procedure	Allow the vial to stand for 15 minutes at room temperature Mix the vial before sampling. Do not fill the cuvette from the vial. Dispense a drop of the control material onto a hydrophobic surface. Fill the cuvette according to the manufacturer's instructions. Wipe any excess material from the vial and the cap with a clean tissue. Recap the vial tightly.	None

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Parameter	Similarities	Differences
Secondary Packaging	Two (2) bottles of the same level are placed in a plastic blister and packed in a product box together with the combined instructions for use (IFU) and value sheet.	None
Storage temperature	2 - 8 degrees Celsius	None
Where used	POC and laboratory	None

Performance Data

Open Stability:

According to the guidelines described in "CLSI-EP25A-2009" at least on batch of a quality control was monitored to determine the in-use stability. One batch of each level was monitored at four (4) time points (n=6) for in total 35 days at 2-8ºC. Based on this study, HemoTrol® WB is stable for 31 days when stored at 2-8ºC.

Closed Stability:

According to guidelines in "CLSI-EP25A-2009" at least 3 batches of a quality control were monitored to determine the shelf life. Three (3) batches of the three HemoTrol® WB levels were monitored at 8 time points for up to 127 days (n=8) at 2-8ºC. The samples used were produced according the regular production process of HemoTrol® WB. The total hemoglobin levels were measured on the HemoCue® Hb 301 and HemoCue® Hb 801 systems. Based on this study, HemoTrol® WB is stable for 108 days when stored at 2-8ºC.

Conclusion

Based on the demonstrated intended use, performance characteristics and comparison of technical characteristics HemoTrol® WB is deemed substantially equivalent to the predicate device: Eurotrol HemoTrol (K964052)

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