November 15, 2019

Eurotrol B.V.
Elisanne Biemans
QA/RA Manager
Keplerlaan 20
EDE, Gelderland, 6716BS NL

Re: K192842
Trade/Device Name: HemoTrol Duo Low, HemoTrol Duo Normal, HemoTrol Duo High
Regulation Number: 21 CFR 864.8625
Regulation Name: Hematology quality control mixture
Regulatory Class: Class II
Product Code: GGM
Dated: September 30, 2019
Received: October 3, 2019

Dear Elisanne Biemans:

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/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,

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)*
K192842

Device Name
HemoTrol® Duo Low,
HemoTrol® Duo Normal and
HemoTrol® Duo High

Indications for Use *(Describe)*
HemoTrol® Duo 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® Duo 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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Eurotrol
Your Global Reference Point for Quality Control

510(K) Summary

HemoTrol Duo

30 September 2019

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.
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T: +31 318 695777
Primary Contact: Ms. Elisanne Biemans, ebiemans@eurotrol.com

Device Information

Device name	REF	Classification
HemoTrol® Duo Low	AN01624A01	Class II (21 CFR 864.8625) GGM – control, Hemoglobin
HemoTrol® Duo Normal	AN01624A02	
HemoTrol® Duo High	AN01624A03	

Predicate Device

Eurotrol HemoTrol® WB
510(k) number: K182744

Device Description

HemoTrol® Duo is an assayed hemoglobin quality control material intended for professional use in the verification of the performance characteristics of the HemoCue® 301 and HemoCue® 801 systems. HemoTrol® Duo contains stroma-free bovine hemolysate with hemoglobin in cyanmethemoglobin (CNMetHb) form and a bioburden-controlling agent. For daily quality control, three physiological relevant levels are available.

HemoTrol® Duo solutions are filled in reclosable plastic primary containers. Each bottle contains 1.0 ml of HemoTrol® Duo 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.

Intended Use

New Device

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

Predicate 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.

The indication for use for HemoTrol® Duo is identical to the predicate device.

Predicate Device Comparison

Parameter	Similarities	Differences
Analyte	Hemoglobin	None
Analyte Concentration	Cover clinical relevant range: Hb301 Analyzer: 70 – 179 g/L Hb801 Analyzer: 65 – 156 g/L	Predicate device also includes: Hb301 Analyzer: not defined Hb801 Analyzer: 95-160 g/L
Color of liquid	Reddish	None
Contents	Purified bovine hemolysate and preservatives.	New 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.	None
Number of Levels	3 levels: Low, Normal, High	None
Open vail stability	31 days at 30°C	31 days at 2-8°C
Primary Container	Reclosable plastic primary containers with polypropylene caps	None
Principle of Operations	The absorbance is measured by using a dual wavelength spectrophotometric technology at 506 and 880 nm.	None
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
Intended user	POC and laboratory	None

Performance Data

Precision/Reproducibility:

Three batches of control material of each of the levels was tested on both analyzers - HemoCue Hb 301 System and HemoCue Hb 801 System. The samples were tested with five replicates per analyzer per day over five operating days on 3 sites. Total precision was within the defined acceptance criteria.

HemoCue Hb301 System

Level	Mean (g/L)	SD (g/L)	CV (%)
Low	70.2	2.0	2.9
Normal	129.8	3.2	2.4
High	168.6	3.8	2.2

HemoCue Hb801 System

Level	Mean (g/L)	SD (g/L)	CV (%)
Low	65.0	1.1	1.7
Normal	117.0	1.5	1.2
High	154.5	1.6	1.0

Open Stability:

Nine (9) batches were monitored to determine the in-use stability. Three (3) batches of each level were monitored at three (3) time points for a total of 34 days at 30ºC. Based on this study, HemoTrol Duo is stable for 31 days when stored at 30ºC.

Closed Stability:

21 batches of a quality control were monitored to determine the shelf life. Three (3) batches of the three HemoTrol Duo levels (9 in total) were monitored up to 337 days at 2-8ºC. The samples used were produced according the regular production process of HemoTrol Duo. The total hemoglobin levels were measured on the HemoCue® Hb 301 and HemoCue® Hb 801 systems. Based on this study, HemoTrol Duo is stable for 336 days when stored at 2-8ºC.

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Expected values and Value Assignment:

Three levels of control solution are available.

For batch acceptance three samples of control materials are evaluated on three HemoCue Hb301 Systems, with three batches of microcuvettes. Each sample is measured once per microcuvette batch, providing 27 replicates per analyzer. If mean value of the 27 measurements performed on the HemoCue Hb301 System is between the 'target acceptance range' (see below) the batch can be released for value assignment.

HemoTrol Duo Level	Production acceptance range on Hb301 (g/L)
Low	70.0 ± 2.5
Normal	130.0 ± 2.5
High	170.0 ± 2.5

When the batch is released for value assignment the three samples of control materials are also evaluated on three HemoCue Hb801 Systems, with three batches of microcuvettes. An assigned value is subsequently determined based on each set of 27 measurements and is thus batch and analyzer specific. To determine the assigned value and range the mean value of the 27 measurements is combined with a fixed range:

HemoTrol Duo Level	Label range (g/L)
Low	Measured mean ± 12
Normal	Measured mean ± 21
High	Measured mean ± 27

Conclusion

Based on the demonstrated intended use, performance characteristics and comparison of technical characteristics HemoTrol® Duo is deemed substantially equivalent to the predicate device: Eurotrol HemoTrol WB (K182744).

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