June 12, 2020

EKF-diagnostic GmbH
Andrew Rutter
Global Head, Quality Assurance & Regulatory Affairs
Ebendorfer Chaussee 3
Barleben, 39179
Germany

Re: K200909
Trade/Device Name: Hemo Control
Regulation Number: 21 CFR 864.5620
Regulation Name: Automated Hemoglobin System
Regulatory Class: Class II
Product Code: GKR
Dated: April 3, 2020
Received: April 6, 2020

Dear Andrew Rutter:

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,

Takeesha Taylor-Bell
Chief
Division of Immunology and Hematology Devices
OHT7: Office of In Vitro Diagnostics and Radiological Health
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)*
k200909

Device Name
Hemo Control

Indications for Use *(Describe)*
Hemo Control is intended to be used for the quantitative determination of hemoglobin (Hb) concentrations in human blood.

The Hemo Control Hemoglobin Microcuvettes are intended to be used with the Hemo Control photometer for the quantitative determination of hemoglobin (Hb) concentrations in human blood.

For in-vitro diagnostic use only.

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.

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510k Summary

Introduction According to the requirements of 21CFR807.92, the following information provides sufficient detail to understand the basis for a determination of substantial equivalence.

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Date Prepared: 24th April 2020

Device Name: Proprietary names:
Hemo Control

Common names: As above.

Classification: 21CFR864.5620 (Class II, Automated hemoglobin system)

Product Code: GKR

Device Descriptions: Hemo Control consists of the Hemo Control photometer / analyzer and the Hemo Control Hemoglobin Microcuvettes, its accessories and consumables (i.e. Control Solution Hb-con).
The Hemo Control photometer / analyzer is a semi-automated, spectrophotometric instrument, which provides instant quantitative total hemoglobin results.
Using the reagent filled microcuvette a small amount of arterial, venous or capillary blood is taken up by capillary action. The filled microcuvette is inserted into the Hemo Control photometer. The color produced by chemical reaction in the microcuvette is measured and the Hb value is displayed.
The measurement accuracy of the Hemo Control Hemoglobin Measurement System can be verified by use of Hb-con control solution, a quality control material with pre-determined hemoglobin concentration.

As a second quality control measurement, the control cuvette as a physical standard is used for a comfortable and cheap check of the device**.**

Predicate Devices: EKF Diagnostic Hemo Control Hemoglobin Measurement System

Predicates 510(k): k031898

Special Conditions for Use: For in vitro diagnostic use.
Rx Only

Special instrument Requirements: None

Intended Use: Hemo Control is intended to be used for the quantitative determination of hemoglobin (Hb) concentrations in human blood.

The Hemo Control Hemoglobin Microcuvettes are intended to be used with the Hemo Control photometer for the quantitative determination of hemoglobin (Hb) concentrations in human blood.

For in-vitro diagnostic use only.

Comparison with predicate:
Similarities and differences compared to the chosen predicate device:-
Hemo Control Hemoglobin System (k031898)

	Predicate Device: Hemo Control	**Candidate Device:** Hemo Control
Model number	3000-0031-6901	3040-0010-0218
Intended Use:	Quantitative determination of hemoglobin	Quantitative determination of hemoglobin
Indications for Use	The Hemo Control Hemoglobin Measurement System is intended to be used for the quantitative determination of hemoglobin (Hb) concentrations in human blood.	Hemo Control is intended to be used for the quantitative determination of hemoglobin (Hb) concentrations in human blood.
Analyte	Hemoglobin	Hemoglobin
Sample requirements	Venous, capillary or arterial blood	Venous, capillary or arterial blood
Methodology	Hem-azide methemoglobin Hct-Estimation from hemoglobin	Hem-azide methemoglobin Hct-Estimation from hemoglobin

Functionality	Data transfer only	Additional data management functionality
Accessory	None	Optional Add Pack Hemo Control DM

Performance Characteristics

Hemo Control

Analytical Performance

a. Precision:

	Within Run (CV)	Total (CV)	Single Observation 20 days (CV)
Hemoglobin/Low (107 g/L)	0.8%	1.0%	0.9%
Hemoglobin/Normal (129 g/L)	0.6%	1.0%	0.8%
Hemoglobin/High (173 g/L)	0.6%	1.1%	1.0%

b. Linearity/assay reportable range:

0 - 25.6 g/dL

c. Traceability (controls, calibrators, or method):

Device calibrated against NCCLS reference method

Comparison studies

a. Method comparison

Comparison to NCCLS Reference Method:
y=1.0064x + 0.0234, r=0.0076, n=174

Comparison to HemoCue hemoglobin measurement system
y=1.0005x – 0.2334, r=0.9962, n=286

Comparison of Hemo Control Cuvettes in HemoCue
y=0.9855x + 0.139, r=0.998, n=286

b. *Matrix comparison*
Capillary samples, 4 sites:
y=0.96x + 0.3742, r=0.8256, n=275

Arterial samples, 1 site:
y=0.9868x – 0.0285, r=0.998, n=10

Expected values/Reference range

Based on literature references

Women: 12.0 – 16.0 g/dl
Men: 13.0 – 17.5 g/dl
Children, depending on age: 9.0 -24 g/dl

Proposed Labeling

The labeling is sufficient and it satisfies the requirements of 21 CFR Part 809.10.

Conclusion

The submitted information in this premarket notification is complete and supports a substantial equivalence decision.