August 4, 2020

HemoCue AB
Maria Fagerberg
Senior Director RA/QA
Kuvettgatan 1
Angelholm, Sweden 26271

Re: K201217
Trade/Device Name: HemoCue Hb 301 System
Regulation Number: 21 CFR 864.5620
Regulation Name: Automated hemoglobin system
Regulatory Class: Class II
Product Code: GKR
Dated: April 30, 2020
Received: May 6, 2020

Dear Maria Fagerberg:

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)*
k201217

Device Name
HemoCue® Hb 301 System

Indications for Use *(Describe)*
The HemoCue® Hb 301 System is intended for quantitative determination of hemoglobin in primary care or blood donation settings.
The HemoCue® Hb 301 System is intended to be used to determine the hemoglobin concentration for adults, adolescents, children, and infants above 1 month old in primary care setting.
The HemoCue® Hb 301 System is intended to be used to determine the hemoglobin concentration for adults in blood donation setting.
The HemoCue® Hb 301 System is for professional 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.

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Enclosure 2

510(k) Summary

1. Submitter and contact information

Submitter:

Company Name:	HemoCue AB
ER Number:	3003044483
Address:	Kuvettgatan 1 SE-262 71 Sweden

Official contact person:

Name:	Maria Fagerberg
Function:	Senior Director RA/QA
E-mail:	maria.fagerberg@hemocue.se
Phone:	+46 431 48 13 46
Mobile:	+46 734 14 03 46
Fax:	+46 431 48 12 25

Secondary contact:

Name:	Andrijana Kankaras
Function:	Regulatory Affairs Specialist
Phone:	+46 431 48 12 26
Fax:	+46 431 48 12 25
E-mail:	andrijana.kankaras@hemocue.se

Date of preparation:

Date:	April 30, 2020

2. Device information

Proprietary name**:**	HemoCue® Hb 301 System
Common name:	Hemoglobin analyzing system
510(k) number:	K061047
Regulation:	Automated hemoglobin system (21 CFR § 864.5620)
Product code:	GKR
Classification:	Class II
Common name:	Hemoglobin analyzing system
Panel:	Hematology

3. Device description

The HemoCue® Hb 301 System provides a direct reading of the hemoglobin concentration in a sample using specially designed, single use microcuvette and an analyzer.
The system can be used by non-laboratory personnel.

The HemoCue® Hb 301 System consists of the following parts:

- An analyzer supporting the following features:
  - Photometric determination of hemoglobin
  - Presentation of results on a display
- Power supply by power adapter or four AA batteries
- Single use microcuvettes (test consumable)
- Labeling:
  - Operating Manual
  - Package Insert
  - Quick reference Guide
  - Labels

The microcuvette serves both as a pipette and as a measuring cuvette. No dilution or other preparation of the blood sample is required before filling of the microcuvette. A whole blood sample of approximately 10 µL is drawn into the cavity in the microcuvette by capillary action.

The measurement takes place in the analyzer, which measures the absorbance of whole blood at an Hb/HbO_2 isosbestic point. The measurement is performed directly on the whole blood through measurement of the transmitted and scattered light and using an algorithm for translation into the hemoglobin concentration of the sample.

The HemoCue® Hb 301 System is traceable to the hemiglobincyanide (HiCN) method, the international reference method according to ICSH for the determination of the hemoglobin concentration in blood.

4. Intended Use and Indications for Use

Intended Use
The HemoCue® Hb 301 System is intended for quantitative determination of hemoglobin in primary care or blood donation settings.
The HemoCue® Hb 301 System is intended to be used to determine the hemoglobin concentration for adults, adolescents, children, and infants above 1 month old in primary care setting.
The HemoCue® Hb 301 System is intended to be used to determine the hemoglobin concentration for adults in blood donation setting.
The HemoCue® Hb 301 System is for professional in vitro diagnostic use only.

Indications for Use
Same as intended use.

5. Substantial Equivalence

	Candidate device	Predicate device
Proprietary name:	HemoCue® Hb 301 System	HemoCue® Hb 801 System
Common name:	Hemoglobin analyzing system	Hemoglobin analyzing system
510(k) number	K061047	K181751
Product code	GKR	GKR
Classification	Class II	Class II
Regulation	21 CFR 864.5620 Automated hemoglobin system	21 CFR 864.5620 Automated hemoglobin system
Classification Panel	Hematology	Hematology

The most important similarities and differences between the HemoCue® Hb 301 System (Candidate Device) and HemoCue® Hb 801 System (Predicate Device) are listed in the table below.

Characteristic	HemoCue® Hb 301 System (Candidate device)	HemoCue® Hb 801 System (Predicate device)
Analyzer		
Microcuvette		

Characteristic	HemoCue® Hb 301 System (Candidate device)	HemoCue® Hb 801 System (Predicate device)
Similarities		
Intended Use	The HemoCue® Hb 301 System is intended for quantitative determination of hemoglobin in primary care or blood donation settings. The HemoCue® Hb 301 System is intended to be used to determine the hemoglobin concentration for adults, adolescents, children, and infants above 1 month old in primary care setting. The HemoCue® Hb 301 System is intended to be used to determine the hemoglobin concentration for adults in blood donation setting. The HemoCue® Hb 301 System is for professional in vitro diagnostic use only.	The HemoCue® Hb 801 System is intended for the quantitative Determination of hemoglobin in capillary or venous whole blood (K_2EDTA and Li-Heparin) in point-of-care settings. The HemoCue® Hb 801 System is intended to be used to determine the hemoglobin concentration for adults, adolescents, children, and infants above 1 month old. The HemoCue® Hb 801 System is for professional in vitro diagnostic use only.
Patient population	Adults, adolescents, children, and infants above 1 month old	Same
Analyte	Hemoglobin	Same
Sample preparation (pre-treatment)	None	Same
Sample volume	10 µL	Same
Measuring principle	Spectrophotometric	Same
Reagent	No active ingredients	Same
Calibration	The system is traceable to the hemiglobincyanide (HiCN) method, according to ICSH. The system is factory calibrated and needs no further calibration.	Same
Quality control	Internal self-test (verifying analyzer performance)	Same
Differences		
Sample type	Capillary, venous or arterial whole blood	Capillary or venous whole blood
Measuring range	0-25.6 g/dL	1-25.6g/dL
Connectivity	Serial port	• Wireless Bluetooth Low Energy (BLE) • USB
Microcuvette insertion technique	Tray	“Slot in”

Characteristic	HemoCue® Hb 301 System (Candidate device)	HemoCue® Hb 801 System (Predicate device)
		
User interface	• Display • Beeper • One button	• Display • Beeper • Two buttons • Status LED

6. Measuring principle

Spectrophotometric

7. Performance Characteristics (if/when applicable)

Analytical performance

Please refer to the initial submission K061047.

Method comparison

In addition to the method comparison studies submitted in K061047, the measurement performance of the HemoCue® Hb 301 System has been evaluated compared to the reference method ICSH with pediatric samples (infants above 1 month old, children and adolescents) according to CLSI EP09c 3rd Edition.

71 pediatric blood samples were tested at one European clinical laboratory site over 7 operating days. Each blood sample was analyzed with 2 replicates on the HemoCue® Hb 301 System and with 3 replicates with the reference method ICSH.

Regression analysis demonstrated comparable performance between the HemoCue® Hb 301 System and ICSH.

In the linear regression analysis of the relationship between HemoCue® Hb 301 System and reference method ICSH, have a slope 0.98 and a correlation coefficient (r) 0.99.

In the linear regression analysis of the relationship between the predicate device HemoCue® Hb 801 System and the HemoCue® Hb 301 System, have a slope 0.97 and a correlation coefficient (r) 0.99, please refer to K181751.

The measurement performance evaluation of the HemoCue® Hb 301 System in comparison to ICSH method fulfills the acceptance criteria for accuracy, and validates the use of the HemoCue® Hb 301 System for samples from children above 1 month old.

Clinical studies

a. Clinical Sensitivity
N/A

b. Clinical specificity
N/A

c. Other clinical supportive data (when a. and b. are not applicable):
N/A

Clinical cut-off

N/A

8. Instrument name

HemoCue® Hb 301 System

9. System Description

a. Mode of operation

The HemoCue® Hb 301 System provides a direct reading of the hemoglobin concentration in a sample using specially designed, single use microcuvette and an analyzer.

The microcuvette serves both as a pipette and as a measuring cuvette. No dilution or other preparation of the blood sample is required before filling of the microcuvette. A whole blood sample of approximately 10 µL is drawn into the cavity in the microcuvette by capillary action.

The measurement takes place in the analyzer, which measures the absorbance of whole blood at an Hb/ HbO_2 isosbestic point. The measurement is performed directly on the whole blood through measurement of the transmitted and scattered light and using an algorithm for translation into the hemoglobin concentration of the sample.

The HemoCue® Hb 301 System is be traceable to the hemiglobincyanide (HiCN) method, the international reference method according to ICSH for the determination of the hemoglobin concentration in blood.

b. Software

Please refer to the initial submission K061047.

c. Specimen Identification

There is no specimen identification function for the HemoCue® Hb 301 System.

d. Specimen Sampling and Handling

A whole blood sample of approximately 10 µL is drawn into the cavity in the HemoCue® Hb 301 Microcuvette by capillary action. To perform a hemoglobin reading, a filled microcuvette is inserted into the microcuvette holder in the HemoCue® Hb 301 Analyzer.

e. Calibration

The HemoCue® Hb 301 System is factory calibrated and needs no further calibration.

f. Quality Controls

The HemoCue® Hb 301 Analyzer has an internal quality control, a self-test. Every time the analyzer is turned on, it will automatically verify the system performance. This test is performed at regular intervals if the analyser remains switched on.

If an external quality control is required by local or other regulations, commercially available controls recommended by HemoCue should be used.

10. Proposed Labeling

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

11. Conclusion

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