November 27, 2018

Acon Laboratories, Inc.
Qiyi Xie
Sr. Staff Regulatory/clinical Affairs
10125 Mesa Rim Road
San Diego, California 92121

Re: K122553
Trade/Device Name: Mission Plus Hb Hemoglobin Testing System
Regulation Number: 21 CFR 864.5620
Regulation Name: Automated hemoglobin system
Regulatory Class: Class II
Product Code: GKR, GGM
Dated: August 17, 2012
Received: August 21, 2012

Dear Qiyi Xie:

This letter corrects our substantially equivalent letter of August 5, 2013.

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

Indications for Use

510(k) Number (if known): K122553 .

Device Name: Mission® Plus Hemoglobin (Hb) Testing System

Indications For Use:

The Mission® Plus Hemoglobin (Hb) Testing System is for the quantitative determination of hemoglobin in non-anticoagulated capillary whole blood or anticoagulated venous whole blood in EDTA (K2, K3, Na2) or sodium heparin. The testing system is designed for point-of-care use in primary care settings. Estimation of hematocrit is only for hemoglobin values from 12.3 to 17.5 g/dL (123 to 175 g/L).

The Mission® Plus Hemoglobin (Hb) Control Solution is intended to validate hemoglobin testing using the Mission® Plus Hemoglobin (Hb) Testing System.

The Mission® Plus Hemoglobin (Hb) Testing System is for professional in vitro diagnostic use only.

Prescription Use __x__ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH; Office of In Vitro Diagnostics and Radiological Health (OIR)

Leonthena R. Carrington -S

Division Sign-Off
Office of In Vitro Diagnostics and Radiological Health

510(k): K122553

K122553

510(k) SUMMARY

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR §864.5620

The Assigned 510(k) number is

Submitter's Identification:

ACON Laboratories, Inc.

10125 Mesa Rim Road

San Diego, California 92121

Tel.: 858-875-8019
Fax: 858-875-8099

AUG 05 2013

Date Prepared: August 2, 2013

Contact Person:

Qiyi Xie
Senior Staff, Clinical & Regulatory Affairs

Proprietary Name of the Device:

Mission® Plus Hemoglobin (Hb) Testing System
Mission® Plus Hemoglobin (Hb) Control Solution

Common Name:

Automated hemoglobin system

Regulatory Information:

1. Regulation section:
   21 CFR 864.5620, Automated hemoglobin system
   21 CFR 862.1660, Quality control material (assayed and unassayed)
2. Classification:
   Class II & I
3. Product Code:
   GKR, JJX
4. Panel:
   Hematology (81)

Predicate Device(s):

Hemopoint H2 Hemoglobin Measurement System,
Stanbio Laboratory
1261 North Main Street, Boerne, Texas 78006
510(k) Number: K032482

Device Name: *Mission® Plus Hemoglobin (Hb) Testing System*

Proprietary Name	Classification	Product Code	Description	Common Name
Mission® Plus Hemoglobin (Hb) Testing System	Class II §864.5620	GKR	System, Test, Hemoglobin Test System,	Hemoglobin Test Meter
Mission® Plus Hemoglobin (Hb) Control Solution	862.1660 Class I	JJX	Analyte Control	Control Solution

Device description:

The Mission® Plus Hemoglobin Testing System consists of The Mission® Hemoglobin (Hb) Testing Meter, *Test cartridge*, Control Solutions, and Optical Verifier.

The *Test cartridges* are used with the Meter for monitoring Hemoglobin (Hb) and estimate the Hematocrit (Hct) within normal range of hemoglobin in capillary or venous whole blood. Red blood cells in the specimen are lysed to release Hb, which is converted into MHb. The shade of the color produced depends on the concentration of Hb.

The Mission® plus Hemoglobin Testing System is a small, portable, battery-powered meter to measure total hemoglobin in combination of disposable test cartridge and requires no sample preparation or reagents. The portable meter analyzes the intensity and color of light reflected from the reagent area of a *Test cartridge* and provides results in less than 15 seconds. The test only requires a single drop of whole blood. The meter can store up to 1,000 results data and the data can be transferred to a computer for further analysis using the USB port. The meter can be powered by 4 AAA (1.5V) batteries or an optional AC adapter.

The *Mission® Plus Hemoglobin (Hb) Testing System* contains an optical verifier which works with the Meter to ensure the optical detection is working properly.

The *Mission® Plus Hemoglobin (Hb) Control Solution* is provided with 3 levels (0, 1, 2,) of control solutions with known concentration of hemoglobin. It is used to confirm that the test meter and *Test cartridges* are working together properly. The product is a liquid, stable control prepared from bovine hemoglobin with added chemicals, preservatives (0.06%) and stabilizers (14.5% of sorbitol and sugar). The control does not contain products of human origins.

Intended Use:

The Mission® Plus Hemoglobin (Hb) Testing System is for the quantitative determination of hemoglobin in non-anticoagulated capillary whole blood or anticoagulated venous whole blood in EDTA (K2, K3, Na2) or sodium heparin. The testing system is designed for point-of-care use in primary care settings. Estimation of hematocrit is only for hemoglobin values from 12.3 to 17.5 g/dL (123 to 175 g/L).

The Mission® Plus Hemoglobin (Hb) Control Solution is intended to validate hemoglobin testing using the Mission® Plus Hemoglobin (Hb) Testing System.

The Mission® Plus Hemoglobin (Hb) Testing System is for professional *in vitro* diagnostic use only.

Technological Characteristics and Substantial Equivalence:

Specification of Blood Hemoglobin Meter:

Features	Specifications
Methodology	Reflectance Photometer
Test Time	<15 seconds
Measurement Range	4.5-25.6 g/dL, 45-256 g/L, 2.8-15.9 mmol/L
Specimen	Whole blood
Specimen Volume	10 µL
Power Source	4 AAA batteries (1.5 V)
	AC Adapter (Mini USB, 5V dc, 50 mA) – Not included
Battery Life	360 hours or 2,700 tests
Units of Measure	g/dL, g/L, mmol/L
Memory	1,000 records
Automatic Shut Off	8 minutes after last action
Meter Size	5.4" × 3.11" ×1.02" (137 mm × 79 mm × 26 mm)
Display Size	1.97" ×1.97" (50 mm × 50 mm)
Weight	145g (without batteries)
Meter Storage Conditions	32 -122 °F (0 - 50 °C); ≤90% RH
Operating Conditions	50 -104 °F (10 - 40 °C); ≤90% RH
Meter Connectors	USB cable for Data Transfer or Power (optional)
Methodology	Reflectance Photometer

Comparison to Predicate Device:

The *Mission® Plus* Hemoglobin (Hb) Testing System and the predicate device are all intended for the quantitative measurement of total hemoglobin in samples of whole blood. No sample preparation or reagents are required. The *Mission® Plus Hemoglobin (Hb) Testing System* is substantially equivalent to Hemopoint H2 Hemoglobin Measurement System, K032482.

Device Comparison Table

Similarities		
Features	**Device**	**Predicate (K032482)**
Intend Use	The Mission® Plus Hemoglobin (Hb) Testing System is for the quantitative determination of hemoglobin in non-anticoagulated capillary whole blood or anticoagulated venous whole blood in EDTA (K2, K3, Na2) or sodium heparin. The testing system is designed for point-of-care use in primary care settings. Estimation of hematocrit is only for hemoglobin values from 12.3 to 17.5 g/dL (123 to 175 g/L). The Mission® Plus Hemoglobin (Hb) Control Solution is intended to validate hemoglobin testing using the Mission® Plus Hemoglobin (Hb) Testing System. The Mission® Plus Hemoglobin (Hb) Testing System is for professional in vitro diagnostic use only.	The HemoPoint H2 Hemoglobin Measurement System is indicated for the quantitative determination of hemoglobin in arterial, venous, or capillary blood. The microcuvettes part number 3010-100 are indicated for use in the HemoPointB H2 Hemoglobin Measurement System and the HemocueB measurement system. The microcuvettes are intended to be used only once and must be disposed of after use as potentially infectious waste. Estimation of hematocrit as a function of Hemoglobin is performed for normal hemoglobin ranges only (120 to 180 g/L or 12.0 to 18.0 g/dL). The estimated hematocrit is not indicative of disease states such as anemia and abnormal values and will not be reported.
Test Detection Principle	Quantitative Reflectance Photometer for measurement of hemoglobin	Same
Visual Display	LCD readout	Same
Calibration	Factory calibrated against CLSI H15-A3 reference method	Same
Recommend testing environment	Doctors' offices	Same

Similarities		
Features	**Device**	**Predicate (K032482)**
Controls	3 levels (0, 1, 2,) of control solutions prepared from bovine hemoglobin with added chemicals, preservatives (0.06%) and stabilizers (14.5% of sorbitol and sugar). The control does not contain products of human origins and may be used for up to 30 days stored at 35°-46°F after opening.	A bi-level reference control set intended for use on Alere HemoPoint® H2 System. Bi-levels (High and Low) of hemoglobin controls are made from animal blood bovine based materials, in reliable liquid form may be used for up to 60 days if stored at 35°-46°F, or 30 days stored at room temperature after opening.
Quality Control Requirements	Users are directed to perform daily optical electronic verification testing and liquid control testing: with each new shipment and/or lot of *Test cartridges*, or when test results are suspect	Users are directed to perform daily electronic quality control testing and liquid control testing: with each new shipment and/or lot of *Test cartridges*, or when test results are suspect .

Units of Measure	g/dL, g/L, mmol/L	Same
Differences		
Features	**Device**	**Predicate (K032482)**
Test Time	⩽15 seconds 10 – 60 seconds	Approximately 30-60sec
Assay Method	Methemoglobin method (Erythrocytes in the specimen are lysed to release hemoglobin by the action of sodium dexycholate. Then the hemoglobin is converted to methemoglobin by the action of sodium nitrite. The intensity of the color produced from this reaction is proportional to the hemoglobin concentration.)	Azidemethemoglobin method (Vanzetti) Hematocrit (Hct)=estimation from hemoglobin
Measurement Range	4.5-25.6 g/dL, (2.8 – 15.9 mmol/L)	0-25.6 g/dL, (0-15.9 mmol/L)
Specimen	Capillary and venous whole blood	Venous, arterial, or capillary blood
Specimen Volume	10 µL	8 µL
Memory	1,000 records	Up to 4,000 records
Meter Connectors	USB (mini) cable for Data Transfer or Power (optional)	No computer connector, only cable for connecting to a specific printer through cox cable. No Data Transfer.
Power supply	AC Power adaptor: Input: 100-240V AC/50-60Hz Output: 5V DC, 50mA 4AAA batteries: Voltage: 6.0V	AC Power adaptor: Input: 100-250V AC/50-60Hz Output: 6V DC Integrated battery: Voltage:2.4V Capacity: 1500mAh
Automatic Shut Off	8 minutes after last use	5 minutes after last use
Meter Size	3.1" ×5.4" × 1" (79×137×26mm) (159 x 165 x 63.5mm)	3.35" × 6.3" × 1.69" (85×160×43mm)
Display Size	2" ×2"(50 mm × 50 mm) 2.25" x 1.25" (57.15 x 31.75mm)	2.19" × 0.81" (21 mm × 55mm)
Weight	0.41 pounds (188g) (with batteries) 1.3	0.77 pounds (350g) (with batteries)
Environmental temperature	50 -104 °F (10 - 40 °C); less than 90% relative humidity (without condensation)	59-86°F (15-30°C), less than 79% relative humidity (without condensation). 59 -86 °F (15 - 30 °C); ≤90% RH

Discussion of Non-Clinical Tests Performed for Determination of Substantial Equivalence are as follows:

The Mission® Plus Hemoglobin (Hb) Testing system underwent electrical safety testing and electromagnetic compatibility testing and was found to be in compliance with applicable

requirements of IEC 61010-1, IEC 61010-2-101, FCC 47 CFR part 15, and EN 61326. Other Non-Clinical Tests Performed for SE are:

1. H3-A6 Procedures for the Collection of Diagnostic Blood Specimens by Venipuncture; Approved Standard-Fourth Edition, CLSI.
2. H4-A4 Procedures and Devices for the Collection of Diagnostic Blood Specimens by Skin Puncture; Approved Standard-Fourth Edition, CLSI.
3. H15-A3 Reference and Selected Procedures for the quantitative Determination of Hemoglobin in Blood; Approved Standard-Third Edition, CLSI.
4. EP09-A2 Method comparison and Bias Estimation Using Patient Samples; Approved Standard-Second Edition, CLSI.
5. EP05-An Evaluation of Precision Performance of Clinical Chemistry Devices; Approved Guideline, CLSI.
6. CLSI EP6-A: Evaluation of the Linearity of Quantitative Measurement Procedures: A Statistical Approach.
7. H20-A2 Reference Leukocyte (WBC) Differential Count (Proportional) and Evaluation of Instrumental Methods; Approved Standard - Second Edition
8. CLSI H26A Performance Goals for the Internal Quality Control of Multichannel Hematology Analyzers; Approved Standard, H26-A
9. CLSI EP7-A2: Interference Testing in Clinical Chemistry; Approved Guideline – Second Edition.
10. FDA Public Health Notification: Use of Fingerstick Devices on More than One Person Poses Risk for Transmitting Bloodborne Pathogens: Initial Communication (2010)
11. CDC Clinical Reminder: Use of Fingerstick Devices on More than One Person Poses Risk or Transmitting Bloodborne Pathogens (2010)
12. US Environmental Protection Agency Office of Pesticide Programs. List D: EPA's Registered Antimicrobial Products Effective Against Human HIV-1 and Hepatitis B Virus (January 9, 2009)

Laboratory Testing:

The performance characteristics of The *Mission® Plus Hemoglobin (Hb) Testing System* were evaluated by performing the following studies: Linearity, Precision, Reproducibility, Accuracy, Interference, Sample volume flex, Sample storage time flex, Operating temperature, Meter Storage temperature, Analytical sensitivity, Hemoglobin (Hb) control value assignment, Control temperatures flex study, Control precision and reproducibility studies, Product stability, (Accelerated and Real time), Safety and Reliability Testing, Low Battery Effect Evaluation, Meter Environment study, Control Solution Environment study, Simulated Shipping Study – *Test cartridge*, Simulated Shipping Study – Control Solution, Virucidal Efficacy Validation Testing and Meter's Cleaning and Disinfection.

Discussion of Clinical Tests Performed:

Clinical studies were conducted at total 4 clinical sites using the *Mission® Plus Hemoglobin (Hb) Testing System* in comparison with predicate device. Health professionals at each site operated the device and the study data were presented for evaluating the system accuracy of The *Mission® Plus Hemoglobin (Hb) Testing System* compared to the results yielded from

predicate device per the ACON Clinical Study Protocol for the Blood Hemoglobin Monitoring System. Study results indicate that intend users were able to obtain comparable blood Hemoglobin readings when using the *Mission® Plus Hemoglobin (Hb) Testing System* as compared to the results obtained from predicate device. In addition, the participants were questioned and responded as satisfied with the ease of operation by following the Instructions for Use in the User's Manual and the overall performance of the *Mission® Plus Hemoglobin (Hb) Testing System.*

Conclusion:

The laboratory testing and clinical study results demonstrate that The *Mission® Plus Hemoglobin (Hb) Testing System* is safe, effective and easy-to-use. It also demonstrates that The *Mission® Plus Hemoglobin (Hb) Testing System* is substantially equivalent to the Hemopoint H2 Hemoglobin Measurement System, 510(k) Number: K032482, currently sold on the U.S. market.