DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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September 13, 2017

Sanguina, LLC
% Cathryn Cambria
Consultant
Cambria Regulatory Consulting, Inc.
5536 Trowbridge Drive
Dunwoody, Georgia 30338

Re: K163215
Trade/Device Name: AnemoCheck
Regulation Number: 21 CFR 864.7500
Regulation Name: Whole blood hemoglobin assays
Regulatory Class: Class II
Product Code: KHG
Dated: July 13, 2017
Received: July 14, 2017

Dear Cathryn Cambria:

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. 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); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and Part 809), please contact the Division of Industry and Consumer Education (DICE) at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. 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 the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education (DICE) at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

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)*
K163215

Device Name
AnemoCheck

Indications for Use *(Describe)*
The AnemoCheck is an in vitro diagnostic semi-quantitative assay for use in point-of-care, clinical and doctor office laboratories for the determination of hemoglobin level and estimation of hematocrit percentage (within normal hemoglobin range) in anticoagulated (K2EDTA, heparin or citrate) whole blood (capillary or venous). AnemoCheck should not be used to evaluate neonatal samples (birth - 1 month).

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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Sanguina, LLC
575 14th Street, NW
Atlanta, GA 30318-5454

K163215

510(k) Summary

This summary of 510(k) safety and effectiveness information is being submitted in accordance with requirements of SMDA 1990 and 21 CFR Part 807.92.

Date : September 7, 2017

1. **Submitter**:

   Sanguina, LLC

   575 14th Street, NW

   Atlanta, GA 30318

2. **Contact Name**:

   Cathryn N. Cambria

   404-543-5909

   ccambria@mindspring.com

3. **Device**:

   Proprietary Name – AnemoCheck™

   Common Name – Whole Blood Hemoglobin Determination

4. **Classifications Names & Citations**:

   Product Code: KHG

   Regulation Number: 864.7500

   Device Class: 2

5. **Predicate Device**:

   Hemocue® Hemoglobin Hb 201+ Analyzing System K032203

   Siemens ® Advia 2120i (K042251)

6. **Device Description**:
The AnemoCheck™ is a semi-quantitative colorimetric assay for determination of total hemoglobin (g/dL) and calculated hematocrit (%) in whole blood. Capillary or venous blood may be used. The assay is rapid (development time is 2 minutes) and is a manual test that does not require electrical power or additional equipment.

7. **Indication for use**:
The AnemoCheck is an *in vitro diagnostic* semi-quantitative assay for use in point-of-care, clinical and doctor office laboratories for the determination of hemoglobin level and estimation of hematocrit percentage (within normal hemoglobin range) in anticoagulated (K2EDTA, heparin or citrate) whole blood (capillary or venous). AnemoCheck should not be used to evaluate neonatal samples (birth - 1 month).

8. **Summary of Non-clinical Testing**:
Bench testing of AnemoCheck versus the predicate device demonstrate substantial equivalence based on accuracy and precision. Interference studies were conducted. Results indicated no significant effects on AnemoCheck test performance.

9. **Assessment of Performance**:
The AnemoCheck is a convenient method for measuring total hemoglobin and calculated hematocrit (%) in whole blood. Test results are comparable to other test methods in clinical laboratory and point-of-care practices.

10. **Conclusions**:
The AnemoCheck™ is similar to other commercially available products based on the intended use, technology, and performance characteristics. In accordance with the Federal Food, Drug and Cosmetic Act, 21 CFR Part 807, and based on the information provided in this premarket notification Sanguina, LLC concludes that AnemoCheck is safe and effective and substantially equivalent to the predicate(s).