September 29, 2023

Sanguina, Inc.
Cathryn Cambria
RA/QA Consultant
147 Technology Parkway Ste 100
Peachtree Corners, Georgia 30092

Re: K221508
Trade/Device Name: AnemoCheck Home
Regulation Number: 21 CFR 864.7500
Regulation Name: Whole Blood Hemoglobin Assays
Regulatory Class: Class II
Product Code: KHG
Dated: May 22, 2022
Received: May 24, 2022

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device"

(https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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,

Min Wu -S

Min Wu, Ph.D.
Branch Chief
Division of Immunology and Hematology Devices
OHT7: Office of In Vitro Diagnostics
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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K221508

Device Name
AnemoCheck Home

Indications for Use *(Describe)*
AnemoCheck Home is intended for home use for the determination of hemoglobin level in whole blood from a finger stick by people over the age of 18. This device is intended for people with anemia caused by iron deficiency anemia, vitamin B12 deficiency anemia, folate deficiency anemia, or who have chronic anemia due to sickle cell disease or thalassemia. AnemoCheck Home tests are for in vitro diagnostic use only. Prescription 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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510(k) Summary

This summary of 510(k) safety and effectiveness information complies with 21 CFR Part 807.92.

Date: 9/27/2023

1. **Submitter**:
   Sanguina, Inc.
   147 Technology Parkway, Ste 100
   Peachtree Corners, GA 30092, USA

2. **Contact Name**:
   Cathryn N. Cambria
   404-543-5909
   ccambria@mindspring.com

3. **Device**:
   Proprietary Name – AnemoCheck Home™
   Common Name – Home Whole Blood Hemoglobin Determination

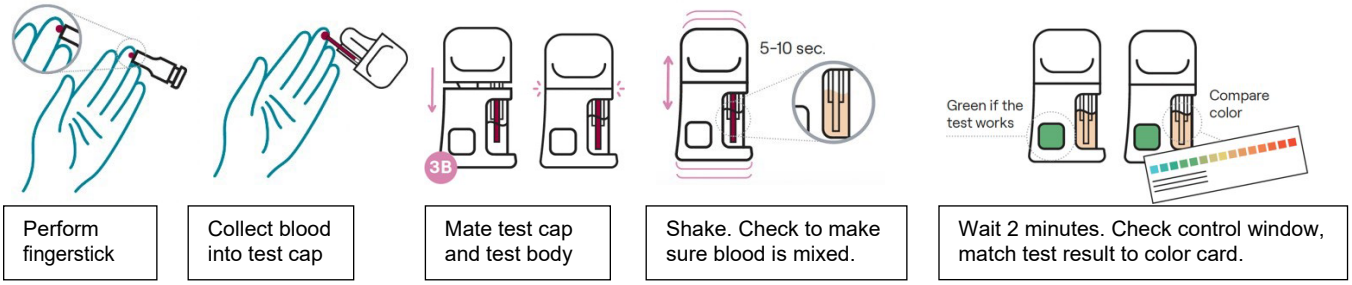
4. **Classifications**
   Product Code: KHG – Whole blood hemoglobin assays
   Regulation section: CFR 864.7500
   Device Classification: Class II

5. **Substantial Equivalence**:
   HemoCue Hemoglobin 201+ System (K032203)
   AnemiaPro Self Screener (K042379)

6. **Device Description**:

   AnemoCheck Home is a home use with prescription anemia test that is semi-quantitative, color based, single use test for hemoglobin level determination. See the simple diagram below for a summary of the steps (Figure 1). Simply, a user performs a finger stick, less than one drop of blood (5uL) is collected into a collection tube within the test cap, the test cap is mated with the test body and shaken. After 2 minutes of development time, the resulting color of the test solution correlates to a color on a color card. The color results correlate to total hemoglobin levels. As shown, the colors range from blue to red (blue and green indicating low hemoglobin levels, yellow indicating slightly decreased hemoglobin levels and orange and red indicating high levels of hemoglobin), with 1.0 g/dL color block resolution. Users may assign values in between two color blocks for a resolution of 0.5 g/dL.

Figure 1. Summary of AnemoCheck Home test use.



AnemoCheck Home is rapid (2 minutes), simple to use, disposable, and is a stand-alone system that does not require electrical power, additional equipment, or training. The device is semi-quantitative and designed to use a specific test body, test cap, blood collection tube and chemical reagent solution. The blood collection tube serves as a pipette and measuring instrument. No dilution is required or measuring is required by the lay user.

AnemoCheck Home leverages the same chemistry and technology used in AnemoCheck (K163215). When blood is mixed with the pre-filled solution, an oxidation-reduction (redox) reaction occurs between 3,3′,5,5′-tetramethylbenzidine (TMB) and hydrogen peroxide, leading to stable oxidized TMB products. The products exhibit different colors based on the amount of total hemoglobin present in the sample. After 2 minutes, the resulting color of the solution then allows for visual interpretation with the naked eye using a color card for determination of hemoglobin (g/dL).

7. **Indication for use**:
AnemoCheck Home is intended for home use for the determination of hemoglobin level in whole blood from a finger stick by people over the age of 18. This device is intended for people with anemia caused by iron deficiency anemia, vitamin B12 deficiency anemia, folate deficiency anemia, or who have chronic anemia due to sickle cell disease or thalassemia. AnemoCheck Home tests are for in vitro diagnostic use only. Prescription Use Only.

8. **Comparison of Technological Characteristics with the Predicate Device**
AnemoCheck Home leverages the same chemistry and technology used in AnemoCheck (K163215). When blood is mixed with the pre-filled solution, an oxidation-reduction (redox) reaction occurs between 3,3′,5,5′-tetramethylbenzidine (TMB) and hydrogen peroxide, leading to stable oxidized TMB products. The products exhibit different colors based on the amount of total hemoglobin present in the sample. After 2 minutes, the resulting color of the solution then allows for visual interpretation with the naked eye using a color

card for determination of hemoglobin (g/dL).

This method is also similar to the oxidation-reduction color-based method used in the HemoCue system.

9. **Summary of Non-clinical Testing**:
Analytical testing of AnemoCheck Home versus the predicate device and comparator methods demonstrate substantial equivalence based on accuracy and precision. Flex study and interference study results indicate no significant effects on AnemoCheck Home test performance.

10. **Assessment of Performance**:
AnemoCheck Home is a convenient method for measuring total hemoglobin in whole blood. Test results in the hands of the intended user, an untrained lay user, are comparable to other test methods in clinical laboratory and point-of-care settings.

11. **Conclusions**:
The AnemoCheck Home is similar to other 510(k) cleared and 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, Inc. concludes that AnemoCheck Home is safe and effective and substantially equivalent to the predicate(s).