December 1, 2023

Sinocare Inc.
Lingjia Zhu
Regulatory Affairs Engineer
No.265 Guyuan Road, Hi-Tech Zone, Changsha, Hunan Province
Changsha, Hunan 410205
China

Re: K231476
Trade/Device Name: TRUENESS™ AIR Blood Glucose Monitoring System; TRUENESS™ Blood Glucose Monitoring System
Regulation Number: 21 CFR 862.1345
Regulation Name: Glucose Test System
Regulatory Class: Class II
Product Code: NBW
Dated: May 22, 2023
Received: May 22, 2023

Dear Lingjia Zhu:

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,

Joshua Balsam -S

Joshua M. Balsam, Ph.D.
Branch Chief
Division of Chemistry
and Toxicology 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)*
K231476

Device Name
TRUENESS™ AIR Blood Glucose Monitoring System

Indications for Use *(Describe)*
The TRUENESS™ AIR Blood Glucose Monitoring System is intended for use in the quantitative measurement of glucose in capillary whole blood from the finger. It is intended for use by people with diabetes mellitus at home as an aid in monitoring the effectiveness of their diabetes control program. The TRUENESS™ AIR Blood Glucose Monitoring System is intended to be used by a single person and should not be shared. It is for in vitro diagnostic use only. The TRUENESS™ AIR Blood Glucose Monitoring System is not intended for the diagnosis of, or screening for diabetes. It is not intended for use on neonates.
The TRUENESS™ AIR Blood Glucose Monitoring System is comprised of the TRUENESS™ AIR blood glucose meter and the TRUENESS™ blood glucose test strip.

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.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

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)*
K231476

Device Name
TRUENESS™ Blood Glucose Monitoring System

Indications for Use *(Describe)*
The TRUENESS™ Blood Glucose Monitoring System is intended for use in the quantitative measurement of glucose in capillary whole blood from the finger. It is intended for use by people with diabetes mellitus at home as an aid in monitoring the effectiveness of their diabetes control program. The TRUENESS™ Blood Glucose Monitoring System is intended to be used by a single person and should not be shared. It is for in vitro diagnostic use only. The TRUENESS™ Blood Glucose Monitoring System is not intended for the diagnosis of, or screening for diabetes. It is not intended for use on neonates.
The TRUENESS™ Blood Glucose Monitoring System is comprised of the TRUENESS™ blood glucose meter and the TRUENESS™ blood glucose test strip.

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)

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Sinocare三诺

510(k) Summary

1. Contact details

510(k) Number:	K231476
Applicant Name:	Sinocare Inc.
Applicant Name:	No.265 Guyuan Road, Hi-tech Zone, Changsha, Hunan Province, 410205, China.
Applicant Contact Telephone:	+86-18890033693
Applicant Contact:	Candy.zhou@sinocare.com
Correspondent Name:	Sinocare Inc.
Correspondent Address:	No.265 Guyuan Road, Hi-tech Zone, Changsha, Hunan Province, 410205, China.
Correspondent Contact Telephone:	+86-15573694818
Correspondent Contact:	Lingjia Zhu
Correspondent Contact email:	lingjia.zhu@sinocare.com
Applicant Contact email:	Candy.zhou@sinocare.com
Prepared on:	11/28/2023

2. Device Name

Trade Name:	TRUENESS™ AIR Blood Glucose Monitoring System; TRUENESS™ Blood Glucose Monitoring
Common Name:	System Blood Glucose Monitoring System
Classification Name:	System, Test, Blood Glucose, Over The Counter
Regulation Number:	862.1345
Product Code:	NBW

3. Legally Marketed Predicate Devices

Contour® next GEN Blood Glucose Monitoring System (K193407)

Product Code:	NBW

4. Device Description Summary

A Device description

The TRUENESS Blood Glucose Monitoring System and TRUENESS AIR Blood Glucose Monitoring System mainly consist of two parts as below:

(1) TRUENESS Blood Glucose Meter or TRUENESS AIR Blood Glucose Meter (With Bluetooth function)

(2) TRUENESS Blood Glucose Test Strip

B Principle of Operation

A glucose test is based on measurement of electrical current caused by the reaction of glucose with flavin adenine dinucleotide (FAD) glucose dehydrogenase on the electrode of the test strip. The blood or control solution sample is drawn into the tip of the TRUENESS Blood Glucose Test Strip through capillary action. Glucose in the sample reacts with the FAD glucose dehydrogenase and generate electrons. The magnitude of the resultant current is proportional to the concentration of glucose in the blood and is converted to a glucose concentration. The glucose concentration is displayed on the meter display for the user.

5. Intended Use/Indications For Use

The TRUENESS™ Blood Glucose Monitoring System is intended for use in the quantitative measurement of glucose in capillary whole blood from the finger. It is intended for use by people with diabetes mellitus at home as an aid in monitoring the effectiveness of their diabetes control program. The TRUENESS™ Blood Glucose Monitoring System is intended to be used by a single person and should not be shared. It is for in vitro diagnostic use only. The TRUENESS™ Blood Glucose Monitoring System is not intended for the diagnosis of, or screening for diabetes. It is not intended for use on neonates.

The TRUENESS™ Blood Glucose Monitoring System is comprised of the TRUENESS™ blood glucose meter and the TRUENESS™ blood glucose test strip.

The TRUENESS™AIR Blood Glucose Monitoring System is intended for use in the quantitative measurement of glucose in capillary whole blood from the finger. It is intended for use by people with diabetes mellitus at home as an aid in monitoring the effectiveness of their diabetes control program. The TRUENESS™AIR Blood Glucose Monitoring System is intended to be used by a single person and should not be shared. It is for in vitro diagnostic use only. The TRUENESS™AIR Blood Glucose Monitoring System is not intended for the diagnosis of, or screening for diabetes. It is not intended for use on neonates.

The TRUENESS™ AIR Blood Glucose Monitoring System is comprised of the TRUENESS™ AIR blood glucose meter and the TRUENESS™ blood glucose test strip.

6. Indications for Use Comparison

The indications for use of the TRUENESS Blood Glucose Monitoring System/TRUENESS AIR Blood Glucose Monitoring System and predicate device are the same.

7. Technological Comparison

Features	**Predicate device**	**Subject Devices**	
	Contour® next GEN (K193407)	**TRUENESS**	**TRUENESS AIR** (with Bluetooth)
Specimen Type	Capillary whole blood	Capillary whole blood	
Where Device Used	Home	Home	
Reagent Form	Electrochemical Test Strip	Electrochemical Test Strip	
Methodology	Electrochemical Biosensor	Electrochemical Biosensor	
Storage Environment	41°F -86°F	41°F -86°F	
Test Time	5 seconds	5 seconds	
Units of Measure	mg/dL	mg/dL	
Reagent Enzyme	FAD- Glucose Dehydrogenase	FAD- Glucose Dehydrogenase	
Averages Calculation	7/14/30/90-day averages	7/14/30/90-day averages	
Test strip calibration	No coding	No coding	
BLE Pairing	Yes	Yes (TRUENESS AIR only)	
Wireless Communication	Bluetooth Low Energy	Bluetooth Low Energy (TRUENESS AIR only)	
Operating Environment	41°F-113°F (5°C-45°C)	50°F-104°F (10°C-40°C)	
Hematocrit Range	20%-55%	15%-60%	
Test Results	Plasma/serum glucose calibrated	Plasma glucose calibrated	
Measurement Range	20 – 600 mg/dL	40 – 600 mg/dL	

Power Source	Two 3-volt CR2032 or DL2032 coin cell batteries	2 AAA alkaline batteries
Sample Size	0.6μL	1μL
Altitude	Up to 20,674 ft	Up to 10,100 ft

8. Non-Clinical and/or Clinical Tests Summary & Conclusions

Design verification and validation testing consisted of performance tests (precision, linearity, interference, flex studies), electrical/mechanical safety tests, as well as disinfection, cleaning, and robustness studies. Software validation studies were performed for moderate level of concern device per FDA Guidance Content of Premarket Submissions for Software Contained in Medical Devices. Results from these studies show that the subject device met design specifications and requirements.

A user evaluation confirmed the system accuracy, operation according to design, and ease of use to support the intended use as described in the proposed labeling.

The conclusions from the nonclinical and clinical tests demonstrated that the device is as safe, as effective, and performs as well as legally marketed device identified above.