October 30, 2026

Changsha Sinocare, Inc.
Jiangqin Zhao
Regulatory Affairs Engineer
#265 Guyuan Rd., Hi-Tech Zone
Changsha, Hunan, CN 410205
China

Re: K260738
Trade/Device Name: Safe AQ Easy Blood Glucose Monitoring System;
Safe AQ Care Blood Glucose Monitoring System
Regulation Number: 21 CFR 862.1345
Regulation Name: Glucose test system
Regulatory Class: Class II
Product Code: NBW
Dated: October 1, 2026
Received: October 1, 2026

Dear Jiangqin Zhao:

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.

Before making any change significantly affecting the safety or effectiveness of the device, you must submit a new premarket notification in accordance with 21 CFR 807.81. 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 Management System Regulation (QMSR) (21 CFR Part 820), which includes, but is not limited to, ISO 13485 clause 7.3 (Design controls), ISO 13485 clause 8.3 (Nonconforming product), ISO 13485 clause 8.5.2 (Corrective action), and ISO 13485 clause 8.5.3 (Preventative action). Please note that regardless of whether a change requires premarket review, the QMSR requires device manufacturers to review and approve changes to device design and production (ISO 13485 clause 7.3 and ISO 13485 clause 7.5) and document changes and approvals in the Medical Device File (ISO 13485 clause 4.2.3).

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 Management System Regulation (QMSR) (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.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

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: 07/31/2026
See PRA Statement below.

510(k) Number *(if known)*
K260738

Device Name
Safe AQ Care Blood Glucose Monitoring System

Indications for Use *(Describe)*
The Safe AQ Care 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 Safe AQ Care 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 Safe AQ Care Blood Glucose Monitoring System is not intended for the diagnosis of, or screening for diabetes. It is not intended for use on neonates.
The Safe AQ Care Blood Glucose Monitoring System is comprised of the Safe AQ Care blood glucose meter and the Safe AQ Care 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: 07/31/2026
See PRA Statement below.

510(k) Number *(if known)*
K260738

Device Name
Safe AQ Easy Blood Glucose Monitoring System

Indications for Use *(Describe)*
The Safe AQ Easy 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 Safe AQ Easy 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 Safe AQ Easy Blood Glucose Monitoring System is not intended for the diagnosis of, or screening for diabetes. It is not intended for use on neonates.
The Safe AQ Easy Blood Glucose Monitoring System is comprised of the Safe AQ Easy blood glucose meter and the Safe AQ Easy blood glucose test strip.

Type of Use *(Select one or both, as applicable)*

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510(k) #: K260738

510(k) Summary

Prepared on: 2026-10-01

Contact Details

21 CFR 807.92(a)(1)

Applicant Name	Changsha Sinocare Inc.
Applicant Address	No.265 Guyuan Road, Hi-Tech Zone Changsha, Hunan CN 410205 China
Applicant Contact Telephone	+86-18890033696
Applicant Contact	Ms. Qian Zhou
Applicant Contact Email	Candy.zhou@sinocare.com
Correspondent Name	Changsha Sinocare Inc.
Correspondent Address	No.265 Guyuan Road, Hi-Tech Zone Changsha, Hunan CN 410205 China
Correspondent Contact Telephone	+86-15581016803
Correspondent Contact	Ms. Jiangqin Zhao
Correspondent Contact Email	Iris.zhao@sinocare.com

Device Name

21 CFR 807.92(a)(2)

Device Trade Name	Safe AQ Easy Blood Glucose Monitoring System; Safe AQ Care Blood Glucose Monitoring System
Common Name	Glucose test system
Classification Name	System, Test, Blood Glucose, Over The Counter
Regulation Number	862.1345
Product Code(s)	NBW

Legally Marketed Predicate Devices

21 CFR 807.92(a)(3)

Predicate #	Predicate Trade Name (Primary Predicate is listed first)	Product Code
K231476	TRUENESS™ Blood Glucose Monitoring System	NBW

Device Description Summary

21 CFR 807.92(a)(4)

A: Device description
a) The Safe AQ Easy Blood Glucose Monitoring System mainly consist of 2 parts as below
(1) Safe AQ Easy Blood Glucose Meter
(2) Safe AQ Easy Blood Glucose Test Strip
b)The Safe AQ Care Blood Glucose Monitoring System mainly consist of 2 parts as below
(1) Safe AQ Care Blood Glucose Meter
(2) Safe AQ Care 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 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.

Intended Use/Indications for Use 21 CFR 807.92(a)(5)

The Safe AQ Easy 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 Safe AQ Easy 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 Safe AQ Easy Blood Glucose Monitoring System is not intended for the diagnosis of, or screening for diabetes. It is not intended for use on neonates.
The Safe AQ Easy Blood Glucose Monitoring System is comprised of the Safe AQ Easy blood glucose meter and the Safe AQ Easy blood glucose test strip.

The Safe AQ Care 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 Safe AQ Care 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 Safe AQ Care Blood Glucose Monitoring System is not intended for the diagnosis of, or screening for diabetes. It is not intended for use on neonates.
The Safe AQ Care Blood Glucose Monitoring System is comprised of the Safe AQ Care blood glucose meter and the Safe AQ Care blood glucose test strip.

Indications for Use Comparison 21 CFR 807.92(a)(5)

The indications for use of the Safe AQ Easy Blood Glucose Monitoring System/Safe AQ Care Blood Glucose Monitoring System and predicate device are the same.

Technological Comparison 21 CFR 807.92(a)(6)

For the technological characteristics, the chemical, principle of operation, energy source of the Safe AQ Easy Blood Glucose Monitoring System/Safe AQ Care Blood Glucose Monitoring System and predicate device are the same. Except the Safe AQ Easy blood glucose meter uses with button batteries. And the physical appearance and materials are different from the predicate device.

Non-Clinical and/or Clinical Tests Summary & Conclusions 21 CFR 807.92(b)

Activities to verify and validate the modification included: disinfection and robustness testing, EMC, electrical safety, hardware functional testing, software functional verification and usability engineering evaluations.
Based on the verification and validation results,the candidate Safe AQ Easy Blood Glucose Monitoring System/Safe AQ Care Blood Glucose Monitoring System are substantially equivalent to the predicate TRUENESS™ Blood Glucose Monitoring System (K231476).