DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

February 16, 2017

ANDON HEALTH CO., LTD
YI LIU
PRESIDENT
NO. 3 JINPING STREET, YA AN ROAD,
NANKAI DISTRICT
TIANJIN 300190 CHINA

Re: K153561
Trade/Device Name: AG-607 Blood Glucose Monitoring System
AG-607 Multi Blood Glucose Monitoring System
Regulation Number: 21 CFR 862.1345
Regulation Name: Glucose test system
Regulatory Class: II
Product Code: NBW, LFR
Dated: January 20, 2017
Received: January 25, 2017

Dear Yi Liu:

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 Parts 801 and 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 regulations (21 CFR Parts 801 and 809), please contact the Division of Industry and Consumer Education 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 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 yours,

Katherine Serrano -S

For: Courtney H. Lias, Ph.D.
Director
Division of Chemistry and Toxicology 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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K153561

Device Name

AG-607 Blood Glucose Monitoring System

Indications for Use *(Describe)*

The AG-607 blood glucose monitoring system is intended to be used for the quantitative measurement of glucose in fresh capillary whole blood samples drawn from the fingertip, palm, forearm, upper arm, calf, or thigh. The AG-607 blood glucose monitoring system is intended to be used by a Single person and should not be shared.

The AG-607 blood glucose monitoring system is intended for self-testing outside the body (in vitro diagnostic use) by people with diabetes at home as an aid to monitor the effectiveness of diabetes control. The AG-607 blood glucose monitoring system should not be used for the diagnosis of or screening for diabetes, nor for neonatal use. Alternative Site Testing (AST) should be done only during steady-state times (when glucose levels is not changing rapidly).

The EGS-2003 test strips are for use with the AG-607 blood glucose meter to quantitatively measure glucose(sugar) in fresh capillary whole blood samples drawn from the fingertips, palm, forearm, upper arm, calf or thigh.

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:

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DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K153561

Device Name

AG-607 Multi Blood Glucose Monitoring System

Indications for Use *(Describe)*

The AG-607Multi blood glucose monitoring system is intended to be used for the quantitative measurement of glucose in fresh capillary whole blood samples drawn from the fingertip, palm, forearm, upper arm, calf, or thigh. The AG-607Multi blood glucose monitoring system is intended for testing outside the body(in vitro diagnostic use) and is intended for multiple-patient use in professional healthcare settings as and aid to monitor the effectiveness of diabetes control program. The system is only used with single-use auto-disabling lancing device.

The AG-607Multi blood glucose monitoring system should not be used for the diagnosis of or screening for diabetes, nor for neonatal use. Alternative Site Testing (AST) should be done only during steady-state times (when glucose levels is not changing rapidly).

The EGS-2003 test strips are for use with the AG-607Multi blood glucose meter to quantitatively measure glucose(sugar) in fresh capillary whole blood samples drawn from the fingertips, palm, forearm, upper arm, calf or thigh.

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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510(k) Summary

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

1.0 Submitter's information

Name: Andon Health Co., Ltd.

Address: No.3 Jinping Street,Ya'an Road, Nankai District, Tianjin, P.R. China

Phone number: 86-22-6052 6161

Fax number: 86-22-6052 6162

Contact: Yi Liu

Date of Preparation: 11/17/2015

2.0 Device information

Trade name: AG-607 Blood Glucose Monitoring System

AG-607 Multi Blood Glucose Monitoring System

Common name: Blood Glucose Monitoring System

Classification name: Blood Glucose Monitoring System

3.0 Classification

Product code	Classification	Regulation Section	Panel
NBW	II	21 CFR 862.1345	Chemistry (75)
LFR	II	21 CFR 862.1345	Chemistry (75)

4.0 Predicate device information

Manufacturer: Andon Medical Co., Ltd.

Device: AG-608N Single Blood Glucose Monitoring System

510(k) number: K110017

5.0 Device description

The AG-607 and AG-607 Multi Glucose Monitoring System (BGMS) consist of blood glucose meter, single use test strips, sterile lancets, lancing device and the control solutions.

They are based on an electrochemical biosensor technology (electrochemical) and the principle of capillary action. Capillary action at the end of the test strip draws the blood into the action chamber and the blood glucose result is displayed in 5 seconds. The control solution available is used to test the performance of the device. It uses the same technological characteristics for testing with its predicate device.

6.0 Intended use

The AG-607 blood glucose monitoring system is intended to be used for the quantitative measurement of glucose in fresh capillary whole blood samples drawn from the fingertip, palm, forearm, upper arm, calf, or thigh. The AG-607 blood glucose monitoring system is intended to be used by a Single person and should not be shared.

The AG-607 blood glucose monitoring system is intended for self-testing outside the body (in vitro diagnostic use) by people with diabetes at home as an aid to monitor the effectiveness of diabetes control. The AG-607 blood glucose monitoring system should not be used for the diagnosis of or screening for diabetes, nor for neonatal use. Alternative Site Testing (AST) should be done only during steady-state times (when glucose levels is not changing rapidly).

The EGS-2003 test strips are for use with the AG-607 blood glucose meter to quantitatively measure glucose(sugar) in fresh capillary whole blood samples drawn from the fingertips, palm, forearm, upper arm, calf or thigh.

The AG-607Multi blood glucose monitoring system is intended to be used for the quantitative measurement of glucose in fresh capillary whole blood samples drawn from the fingertip, palm, forearm, upper arm, calf, or thigh. The AG-607Multi blood glucose monitoring system is intended for testing outside the body(in vitro diagnostic use) and is intended for multiple-patient use in professional healthcare settings as and aid to monitor the effectiveness of diabetes control program. The system is only used with single-use auto-disabling lancing device.

The AG-607Multi blood glucose monitoring system should not be used for the diagnosis of or screening for diabetes, nor for neonatal use. Alternative Site Testing (AST) should be done only during steady-state times (when glucose levels is not changing rapidly).

The EGS-2003Multi test strips are for use with the AG-607Multi blood glucose meter to quantitatively measure glucose(sugar) in fresh capillary whole blood samples drawn from the fingertips, palm, forearm, upper arm, calf or thigh.

7.0 Summary comparing technological characteristics with predicate device

CHARACTERISTICS	NEW DEVICE: AG-607 Blood Glucose Monitoring System	PREDICATE: AG-608N Single Blood Glucose Monitoring System (K110017)
Detection Method	Amperometry	Amperometry
Enzyme	Glucose dehydrogenase	Glucose Oxidase
Type of Meter	Biosensor (Electrode)	Biosensor (Electrode)
Sample Source	Capillary whole blood from AST(Alternative site testing) and finger	Capillary whole blood from AST(Alternative site testing) and finger
Sample Application	Blood sample is placed directly to the test strip after finger or AST is lanced.	Blood sample is placed directly to the test strip after finger or AST is lanced.
Hematocrit Range	20-60%	20-60%
Operating Temperature Range	10℃～40℃(50°-104°F)	10℃～40℃(50°-104°F)
Dimensions	110mm x 52mm x 20.5mm	87mm×53mm ×9.9mm
Display	LCD	LCD
Result Presentation	mg/dL or mmol/L	mg/dL or mmol/L
Memory Capabilities	500 times	500 times
Test Start	Automatic	Automatic
Test Time	5 second	5 second
Power Source	DC3.0V (2×LR03)	DC 3.0V (CR2032)
Battery Life	1000 times	500 times
Measurement Range	20mg/dL-600mg/dL (1.1mmol/L~33.3mmol/L)	20mg/dL-600mg/dL (1.1mmol/L~33.3mmol/L)
Qualified Test Strip	EGS-2003 Test Strip	AGS-1000N Test Strip

Sample Volume	Minimum 0.7 micro liter	Minimum 0.7 micro liter
Connect Method	NA	USB
Outlook	See Picture 1	See Picture 2

Picture 1: AG-607

Picture 2 AG-608N

8.0 Performance summary

The AG-607 and AG-607 Multi Blood Glucose Monitoring System (BGMS) conform to the following standards:

- ISO 15197: In vitro diagnostic test systems- Requirements for blood-glucose monitoring systems for self-testing in managing diabetes mellitus.

Non-clinical test and the clinical test are done according to the above standard.

9.0 Comparison to the predict device and the conclusion

The proposed device AG-607 is similar with the predicate device AG-608N, they are both for single patient use, and can test the blood glucose at the alternative site. The hematocrit range, the use function are all the same. The appearance, internal power source and the qualified test strip of the two device is different. Moreover, the new device AG-607 meter does not have the USB function.

However, the test in this submission provides demonstration that these small differences do not raise any new questions of safety and effectiveness.