K093262

JUL 13 2010

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 Medical Co., Ltd.
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Phone number: 86-22-8761 2426
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Contact: Yi Liu
Date of Application: 09/30/2009

2.0 Device information

Trade name: AG-608 Blood Glucose Monitoring System
AG-610 Blood Glucose Monitoring System
Common name: Blood Glucose Monitoring System
Classification name: Blood Glucose Monitoring System

3.0 Classification

Production code: NBW- Blood Glucose Monitoring System.
Regulation number: 862:1345
Classification: II
Panel: Clinical Chemistry

4.0 Predict device information

Manufacturer: Andon Health Co., Ltd.
Device: AG-606 Blood Glucose Monitoring System
510(k) number: k073030

5.0 Device description

AG-608, AG-610 Blood Glucose Monitoring System consists of a blood glucose meter, test strips, lancets, lancing device and the control solutions (available if user requests).

The AG-608, AG-610 blood Glucose Monitoring system is 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 are used to test the performance of the device.

6.0 Intended use

AG-608, AG-610 Blood Glucose Monitoring System is intended for the quantitative measurement of glucose in fresh capillary whole blood from the finger only. Testing is done outside the body (In Vitro diagnostic use). It is indicated for both lay uses by people with diabetes and in a clinical setting by health care professionals, as an aid to monitoring levels in Diabetes Mellitus. Not for use on neonates. It is not intended for the diagnosis of or screening for diabetes mellitus.

7.0 Summary comparing technological characteristics with predicate device

Similarities		
CHARACTERISTICS	**NEW DEVICE: AG-608 Blood Glucose Monitoring System**	**PREDICATE: AG-606 Blood Glucose Monitoring System** (K073030)
Detection Method	Amperometry	Amperometry
Enzyme	Glucose Oxidase	Glucose Oxidase
Type of Meter	Biosensor (Electrode)	Biosensor (Electrode)
Intended Use	To quantitatively measure glucose in fresh capillary whole blood.	To quantitatively measure glucose in fresh capillary whole blood.
Sample Source	Capillary whole blood	Capillary whole blood
Sample Application	Blood sample is placed directly to the test strip after finger is lanced.	Blood sample is placed directly to the test strip after finger is lanced.
Hematocrit Range	30-55%	30-55%
Operating Temperature Range	10℃~40℃(50°-104°F)	10℃~40℃(50°-104°F)
Dimensions	85mmx 53mmx 13. 7mm	82mmx 59mmx 20mm
Display	LCD	LCD
Result Presentation	mg/dL or mmol/L	mg/dL or mmol/L
Memory Capabilities	350 times with time and date displaying	350 times with time and date displaying
Test Start	Automatic	Automatic
Test Time	5 second	5 second
Power Source	DC 3V (CR2032)	DC 3V (2 AAA)
Battery Life	Approx. 1000 normal tests	Approx. 1000 normal tests

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	AGS-1000 Test Strip	AGS-600 Test Strip
Sample Volume	Minimum 0.7 microliter	Minimum 1 microliter
Other function	Code bottle	N/A

CHARACTERISTICS	**NEW DEVICE: AG-610 Blood Glucose Monitoring System**	**PREDICATE: AG-606 Blood Glucose Monitoring System (K073030)**
Detection Method	Amperometry	Amperometry
Enzyme	Glucose Oxidase	Glucose Oxidase
Type of Meter	Biosensor (Electrode)	Biosensor (Electrode)
Intended Use	To quantitatively measure glucose in fresh capillary whole blood.	To quantitatively measure glucose in fresh capillary whole blood.
Sample Source	Capillary whole blood	Capillary whole blood
Sample Application	Blood sample is placed directly to the test strip after finger is lanced.	Blood sample is placed directly to the test strip after finger is lanced.
Hematocrit Range	30-55%	30-55%
Operating Temperature Range	10℃~40℃(50°-104°F)	10℃~40℃(50°-104°F)
Dimensions	134mmx 64mmx 43mm	82mmx 59mmx 20mm
Display	LCD	LCD
Result Presentation	mg/dL or mmol/L	mg/dL or mmol/L
Memory Capabilities	350 times with time and date displaying	350 times with time and date displaying
Test Start	Automatic	Automatic
Test Time	5 second	5 second
Power Source	DC3V (2XAAA batteries)	DC 3V (2 AAA)
Battery Life	Approx. 1000 normal tests	Approx. 1000 normal tests
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	AGS-1000 Test Strip	AGS-600 Test Strip
Sample Volume	Minimum 0.7 micro liter	Minimum 1 microliter
Other function	Code bottle	N/A

8.0 Performance summary

AG-608, AG-610 blood glucose monitoring system 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

AG-608 and AG-610 is very similar with the predicted device AG-606, However, their appearance is different from AG-606, they use the different test strips, they also has a code button.

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

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food & Drug Administration
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Tianjin, China 300190

JUL 13 2010

Re: k093262
Trade name: AG-608 Blood Glucose Monitoring System
AG-610 Blood Glucose Monitoring System
Regulation Number: 21 CFR 862.1345
Regulation Name: Glucose Test System
Regulatory Class: Class II
Product Code: NBW, CGA, JJX
Dated: June 25, 2010
Received: June 25, 2010

Dear Mr. 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.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. 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); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820).

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of *In Vitro* Diagnostic Device Evaluation and Safety at (301) 796-5450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (301) 796-5760. 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 Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-5680 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Courtney C. Harper, Ph.D.
Director
Division of Chemistry and Toxicology
Office of *In Vitro* Diagnostic Device
Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

Indication for Use

510(k) Number (if known): K093262

Device Name: AG-608 Blood Glucose Monitoring System
AG-610 Blood Glucose Monitoring System

Indication For Use:

AG-608, AG-610 Blood Glucose Monitoring System is intended for the quantitative measurement of glucose in fresh capillary whole blood from the finger only. Testing is done outside the body (In Vitro diagnostic use). It is intended for use by healthcare professionals and people with diabetes mellitus at home as an aid in monitoring the effectiveness of a diabetes control program. Not for use on neonates. It is not intended for the diagnosis of or screening for diabetes mellitus.

Prescription Use Yes (21 CFR Part 801 Subpart D)	And/Or	Over the Counter Use Yes (21 CFR Part 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE; CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Device Evaluation and Safety (OIVD)

Carol C Benson

Division Sign-Off
Office of In Vitro Diagnostic Device
Evaluation and Safety

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