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AUG - 9 2011

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.
Address: No.04-23-3 AIRPORT INDUSTRIAL PARK, TIANJIN
Phone number: 86-22-8761 2426
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Contact: Yi Liu
Date of Application: 5/9/2010

2.0 Device name

AG-6081 Single Blood Glucose Monitoring System
AG-6951 Single Blood Glucose Monitoring System
AG-6081 MULTI Blood Glucose Monitoring System
AG-6951 MULTI 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 Intended use

5.1 AG-6081 Single and AG-6951 Single BGMS

The AG-6081 Single Blood Glucose Monitoring System is intended to be used

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for the quantitative measurement of glucose in fresh capillary whole blood samples drawn from the fingertip, palm, forearm, upper arm, calf and thigh. The AG-6081 Single Blood Glucose Monitoring System is to be used by a single person and should not be shared.

The AG-6081 Single 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-6081 Single Blood Glucose Monitoring System should not be used for the diagnosis of or screening for diabetes, nor for neonatal use. Alternative site testing should be done only during steady - state times (when glucose is not changing rapidly).

The AGS-1100 Single Blood Glucose Test Strips are for use with the AG-6081 Single Blood Glucose Meter to quantitatively measure glucose in fresh capillary whole blood samples drawn from the fingertips, palm, forearm, upper arm, calf and thigh.

The AGS-1100 Glucose Controls are intended for in vitro diagnostic use (i.e. for external use only) by healthcare professionals and in the home by people with diabetes mellitus to assess the performance of the AG-6081 Single meters and AGS-1100 Single test strips.

The AG-6951 Single 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 and thigh. The AG-6951 Single Blood Glucose Monitoring System is to be used by a single person and should not be shared.

The AG-6951 Single 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-6951 Single Blood Glucose Monitoring System should not be used for the diagnosis

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of or screening for diabetes, nor for neonatal use. Alternative site testing should be done only during steady - state times (when glucose is not changing rapidly).

The AGS-1100 Single Blood Glucose Test Strips are for use with the AG-6951 Single Blood Glucose Meter to quantitatively measure glucose in fresh capillary whole blood samples drawn from the fingertips, palm, forearm, upper arm, calf and thigh.
The AGS-1100 Glucose Controls are intended for in vitro diagnostic use (i.e. for external use only) by healthcare professionals and in the home by people with diabetes mellitus to assess the performance of the AG-6951 Single meters and AGS-1100 Single test strips.

This system contains a speaking function that provides audible test results for users with impaired vision. The audible function does not provide complete instructions for all functions of the meter or for performing a glucose test.

5.2 AG-6081 MULTI and AG-6951 MULTI BGMS

The AG-6081 MULTI 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 and thigh. The AG-6081 MULTI 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 an aid to monitor the effectiveness of a diabetes control program.

The AG-6081 MULTI Blood Glucose Monitoring System should not be used for the diagnosis of or screening for diabetes, nor for neonatal use. Alternative site testing such as the palm, forearm, upper arm, calf and thigh should be done only during steady – state times (when glucose is not changing rapidly).

The AGS-1100 MULTI Blood Glucose Test Strips are for use with the AG-6081 MULTI Blood Glucose Meter to quantitatively measure glucose in fresh capillary whole blood samples drawn from the fingertips, palm, forearm, upper

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arm, calf and thigh.

The AGS-1100 Glucose Controls are intended for in vitro diagnostic use (i.e. for external use only) by healthcare professionals and in the home by people with diabetes mellitus to assess the performance of the AG-6081 MULTI meters and AGS-1100 MULTI test strips.

The AG-6951 MULTI 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 and thigh. The AG-6951 MULTI 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 an aid to monitor the effectiveness of a diabetes control program.

The AG-6951 MULTI Blood Glucose Monitoring System should not be used for the diagnosis of or screening for diabetes, nor for neonatal use. Alternative site testing such as the palm, forearm, upper arm, calf and thigh should be done only during steady – state times (when glucose is not changing rapidly).

The AGS-1100 MULTI Blood Glucose Test Strips are for use with the AG-6951 MULTI Blood Glucose Meter to quantitatively measure glucose in fresh capillary whole blood samples drawn from the fingertips, palm, forearm, upper arm, calf and thigh.

The AGS-1100 Glucose Controls are intended for in vitro diagnostic use (i.e. for external use only) by healthcare professionals and in the home by people with diabetes mellitus to assess the performance of the AG-6951 MULTI meters and AGS-1100 MULTI test strips.

This system contains a speaking function that provides audible test results for users with impaired vision. The audible function does not provide complete instructions for all functions of the meter or for performing a glucose test.

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6.0 Device description

AG-6081 and AG-6951 Single Blood Glucose Monitoring System (BGMS) consist of blood glucose meter, single use test strips, sterile lancets, lancing device and the control solutions.

While AG-6081 and AG-6951 MULTI Blood Glucose Monitoring System (BGMS) consist of blood glucose meter, MULTI use test strips, Auto-disabling Lancing device and the control solutions.

The four blood Glucose Monitoring system AG-6081 Single, AG-6951 Single, AG-6081 MULTI and AG-6951 MULTI are all 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. All of them use the same technological characteristics for testing with their predicate device. Only the appearance is different from their predicate device, and the new devices can test the blood glucose at the alternative site: the palm, the forearm, the upper arm, the calf and the thigh.
More over, AG-6951 Single and AG-6951 MULTI Blood Glucose Monitoring Systems have a voice function, which is also different from their predicate device.

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7.0 Summary comparing technological characteristics with predicate device

7.1 AG-6081 Single and AG-6081 MULTI BGMS

Similarities		
CHARACTERISTICS	**NEW DEVICE:** **AG-6081 Single and AG-6081 MULTI 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)
Operating Temperature Range	10℃～40℃(50°-104°F)	10℃～40℃(50°-104°F)
Display	LCD	LCD
Result Presentation	mg/dL or mmol/L	mg/dL or mmol/L
Test Start	Automatic	Automatic
Test Time	5 seconds	5 seconds
Battery Life	Approx. 500 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)
Differences		
CHARACTERISTICS	**AG-6081 Single and AG-6081 MU MULTI Blood Glucose Monitoring System**	**AG-606 Blood Glucose Monitoring System** (K073030)
Sample Source	AST(Alternative site testing)	Capillary whole blood
Hematocrit Range	20-60%	30-55%
Dimensions	87mmx 53mmx 9.9mm	82mmx 59mmx 20mm
Memory Capabilities	500 times with time and date displaying	350 times with time and date displaying
Power Source	DC 3V (CR2032)	DC 3V (2 AAA)
Qualified Test Strip	AGS-1100 Single Test strip for AG-6081 Single BGMS and AGS-1100 MULTI Test Strip for AG-6081 MULTI BGMS	AGS-600 Test Strip
Sample Volume	Minimum 0.7 micro liter	Minimum 1 micro liter
Other function	USB function.	N/A

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Intended Use	To quantitatively measure glucose.	To quantitatively measure glucose in fresh capillary whole blood.
Sample Application	Blood sample is placed directly to the test strip after finger or other part of the body is lanced.	Blood sample is placed directly to the test strip after finger is lanced.

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7.2 AG-6951 Single and AG-6951 MULTI BGMS

Similarities		
CHARACTERISTICS	**NEW DEVICE:** **AG-6951 Single and AG-6951 MULTI 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)
Operating Temperature Range	10℃～40℃(50°-104°F)	10℃～40℃(50°-104°F)
Display	LCD	LCD
Result Presentation	mg/dL or mmol/L	mg/dL or mmol/L
Test Start	Automatic	Automatic
Test Time	5 second	5 second
Power Source	DC 3V (2 AAA)	DC 3V (2 AAA)
Measurement Range	20mg/dL-600mg/dL (1.1mmol/L~33.3mmol/L)	20mg/dL-600mg/dL (1.1mmol/L~33.3mmol/L)
Differences		
CHARACTERISTICS	**NEW DEVICE: AG-6951 Blood Glucose Monitoring System**	**PREDICATE: AG-606 Blood Glucose Monitoring System (K073030)**
Intended Use	To quantitatively measure glucose.	To quantitatively measure glucose in fresh capillary whole blood.
Sample Source	AST(Alternative site testing)	Capillary whole blood
Sample Application	Blood sample is placed directly to the test strip after finger or other part of the body is lanced.	Blood sample is placed directly to the test strip after finger is lanced.
Hematocrit Range	20-60%	30-55%
Dimensions	52mmx 92mmx 21mm	82mmx 59mmx 20mm
Memory Capabilities	500 times with time and date displaying	350 times with time and date displaying
Battery Life	Approx. 500 normal tests	Approx. 1000 normal tests
Qualified Test Strip	AGS-1100 Single Test strip for AG-6951 Single BGMS	AGS-600 Test Strip

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	and AGS-1100 MULTI Test Strip for AG-6951 MULTI BGMS	
Sample Volume	Minimum 0.7 microliter	Minimum 1 microliter
Other function	Voice function	N/A

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8.0 Performance summary

AG-6081 Single BGMS, AG-6081 MULTI BGMS, AG-6951 Single BGMS and AG-6951 MULTI 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.
- FDA Draft Guidance Document-Total Product Life Cycle for Portable Invasive Blood Glucose Monitoring Systems: October 24, 2006
- CLSI/NCCLS Guideline, EP07-A2 Interference Testing in Clinical Chemistry; Approved Guideline-Second edition

9.0 Comparison to the predict device and the conclusion

The four blood glucose monitor AG-6081 Single, AG-6081 MULTI, AG-6951 Single and AG-6951 MULTI are very similar with the predicate device AG-606. Their appearance is different from AG-606, they use the different test strips, and the intended use of AG-6081 MULTI and AG-6951 MULTI Blood Glucose Monitoring Systems are also different from their predicate device AG-606. Besides, the four new devices can test the blood glucose at the alternative site other than the finger, and they have the USB function as well. More over, AG-6951 Single and AG-6951 MULTI BGMS have a new voice function.

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 and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993

Andon Medical Co., Ltd.
c/o Yi Liu
No. 04-23-3 Airport Industrial Park
Tianjin, China 300381

AUG 09 2011

Re: k101307
Trade name: AG-6081 Single Blood Glucose Monitoring System
AG-6081 Multi Blood Glucose Monitoring System
AG-6951 Single Blood Glucose Monitoring System
AG-6951 Multi Blood Glucose Monitoring System
AGS-1100 Control Solution
Regulation Number: 21 CFR 862.1345
Regulation Name: Glucose Test System
Regulatory Class: Class II
Product Code: NBW, CGA, JJX
Dated: July 25, 2011
Received: July 28, 2011

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.

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 Parts 801 and 809), 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 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) 796-7100 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Courtney 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): K101307

Device Name: AG-6081 Single Blood Glucose Monitoring System

Indication for Use:

The AG-6081 Single 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 and thigh. The AG-6081 Single Blood Glucose Monitoring System is to be used by a single person and should not be shared.

The AG-6081 Single 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-6081 Single Blood Glucose Monitoring System should not be used for the diagnosis of or screening for diabetes, nor for neonatal use. Alternative site testing should be done only during steady – state times (when glucose is not changing rapidly).

The AGS-1100 Single Blood Glucose Test Strips are for use with the AG-6081 Single Blood Glucose Meter to quantitatively measure glucose in fresh capillary whole blood samples drawn from the fingertips, palm, forearm, upper arm, calf and thigh.

The AGS-1100 Glucose Controls are intended for in vitro diagnostic use (i.e. for external use only) by healthcare professionals and in the home by people with diabetes mellitus to assess the performance of the AG-6081 Single meters and AGS-1100 Single test strips.

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

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

510(k) K101307

Indication for Use

510(k) Number (if known): K101307

Device Name: AG-6081 MULTI Blood Glucose Monitoring System

Indication For Use:

The AG-6081 MULTI 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 and thigh. The AG-6081 MULTI 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 an aid to monitor the effectiveness of a diabetes control program.

The AG-6081 MULTI Blood Glucose Monitoring System should not be used for the diagnosis of or screening for diabetes, nor for neonatal use. Alternative site testing such as the palm, forearm, upper arm, calf and thigh should be done only during steady – state times (when glucose is not changing rapidly).

The AGS-1100 MULTI Blood Glucose Test Strips are for use with the AG-6081 MULTI Blood Glucose Meter to quantitatively measure glucose in fresh capillary whole blood samples drawn from the fingertips, palm, forearm, upper arm, calf and thigh.

The AGS-1100 Glucose Controls are intended for in vitro diagnostic use (i.e. for external use only) by healthcare professionals and in the home by people with diabetes mellitus to assess the performance of the AG-6081 MULTI meters and AGS-1100 MULTI test strips.

Prescription Use √ And/Or Over the Counter Use √

(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

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

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Ruth Chesler

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Office of In Vitro Diagnostic Device
Evaluation and Safety

510(k) K101307

Indication for Use

510(k) Number (if known): K101307

Device Name: AG-6951 Single Blood Glucose Monitoring System

Indication For Use:

The AG-6951 Single 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 and thigh. The AG-6951 Single Blood Glucose Monitoring System is to be used by a single person and should not be shared.

The AG-6951 Single 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-6951 Single Blood Glucose Monitoring System should not be used for the diagnosis of or screening for diabetes, nor for neonatal use. Alternative site testing should be done only during steady – state times (when glucose is not changing rapidly).

The AGS-1100 Single Blood Glucose Test Strips are for use with the AG-6951 Single Blood Glucose Meter to quantitatively measure glucose in fresh capillary whole blood samples drawn from the fingertips, palm, forearm, upper arm, calf and thigh.
The AGS-1100 Glucose Controls are intended for in vitro diagnostic use (i.e. for external use only) by healthcare professionals and in the home by people with diabetes mellitus to assess the performance of the AG-6951 Single meters and AGS-1100 Single test strips.

This system contains a speaking function that provides audible test results for users with impaired vision. The audible function does not provide complete instructions for all functions of the meter or for performing a glucose test.

Prescription Use √ And/Or Over the Counter Use √

(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

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

Ruth Chesler

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

510(k) 101307

Indication for Use

510(k) Number (if known): K101307

Device Name: AG-6951 MULTI Blood Glucose Monitoring System

Indication For Use:

The AG-6951 MULTI 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 and thigh. The AG-6951 MULTI 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 an aid to monitor the effectiveness of a diabetes control program.

The AG-6951 MULTI Blood Glucose Monitoring System should not be used for the diagnosis of or screening for diabetes, nor for neonatal use. Alternative site testing such as the palm, forearm, upper arm, calf and thigh should be done only during steady – state times (when glucose is not changing rapidly).

The AGS-1100 MULTI Blood Glucose Test Strips are for use with the AG-6951 MULTI Blood Glucose Meter to quantitatively measure glucose in fresh capillary whole blood samples drawn from the fingertips, palm, forearm, upper arm, calf and thigh.

The AGS-1100 Glucose Controls are intended for in vitro diagnostic use (i.e. for external use only) by healthcare professionals and in the home by people with diabetes mellitus to assess the performance of the AG-6951 MULTI meters and AGS-1100 MULTI test strips.

This system contains a speaking function that provides audible test results for users with impaired vision. The audible function does not provide complete instructions for all functions of the meter or for performing a glucose test.

Prescription Use √ And/Or Over the Counter Use √

(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

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

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510(k) K101307