K123935

APR 1 2 2013

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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Contact: Yi Liu

Date of Application: 12/14/2012

2.0 Device information

Trade name: iHealth BG5 Wireless Smart Gluco-Monitoring System

iHealth BG5L Wireless Smart Gluco-Monitoring System

Common name: Blood Glucose Monitoring System

Classification name: Blood Glucose Monitoring System

3.0 Classification

Product Code	Classification	Regulation Section	Panel
NBW- Blood Glucose Monitoring System.	Class II	862.1345	Clinical Chemistry
CGA- test, blood glucose, over the counter	Class II	862.1345	Clinical Chemistry
JQP- calculator/data processing module, for clinical use.	Class I	862.2100	Clinical Chemistry
JJX- single (specified) analyte controls (assayed and unassayed)	Class I	862.1660	Clinical Chemistry

4.0 Predicate device information

1	Manufacturer:	Andon Medical Co., Ltd.
	Device:	iHealth BG3 Smart Gluco-monitoring System
	510(k) number:	k120813
2	Manufacturer:	Andon Medical Co., Ltd.
	Device:	AG-608N Blood Glucose monitoring System
	510(k) number:	k110017

5.0 Device description

iHealth BG5 and BG5L Wireless Smart Gluco-Monitoring System consist of blood glucose meter, single use test strips, sterile lancets, lancing device and the control solutions.

The new device iHealth BG5 and BG5L Wireless Smart Glucose meters 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.

The new device iHealth BG5 and BG5L meters can display the test results itself, it can also transmit the test results to the an iPhone, iPod touch or iPad through blue tooth.

6.0 Intended use

iHealth BG5 and BG5L wireless Smart Gluco-Monitoring System is intended to be used for:

- quantitative measurement of glucose in fresh capillary whole blood samples drawn from the fingertip, palm, forearm, upper arm, calf or thigh
- single person measurement only and should not be shared
- 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

iHealth BG5 and BG5L wireless Smart Gluco-Monitoring System should

not be used for the diagnosis of or screening for diabetes, or for neonatal use.

Alternative Site Testing (AST) should be done only during steady state times when glucose levels are not changing rapidly.

The AGS1000I test strips are intended for use with the iHealth BG5 and BG5L meter to quantitatively measure glucose in fresh capillary whole blood samples drawn from the fingertips, palm, forearm, upper arm, calf or thigh using the iHealth BG5 and BG5L meter.

The iHealth control solutions are intended for use with the iHealth BG5/BG5L Blood Glucose Monitoring System, to check that the glucose meter and test strips are working properly. These solutions contain a known range of glucose, as indicated on the bottles.

The iHealth Gluco-Smart App is an iOS app for iPhone, iTouch, and iPad and is used for data extraction and analysis in iHealth BG5 and BG5L Wireless Smart Gluco-Monitoring System.

7.0 Summary comparing technological characteristics with predicate device

CHARACTERISTICS	NEW DEVICE: iHealth BG5 and BG5L wireless Smart Gluco-Monitoring System	PREDICATE: iHealth BG3 Smart Gluco-Monitoring System(K120813)
Detection Method	Amperometry	Amperometry
Enzyme	Glucose Oxidase	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℃～35℃(50°-95°F)	10℃～35℃(50°-95°F)
Dimensions	9mm × 34.5mm ×19mm	102mm×58mm ×22mm
Display	LED display, Display on iPhone, iPod	Connect to iPone or iPod touch to display

	touch or iPad connected through Bluetooth	measurement results
Result Presentation	mg/dL or mmol/L	mg/dL or mmol/L
Memory Capabilities	500 times with time and date displaying	10000 times with time and date displaying
Test Start	Automatic	Automatic
Test Time	5 second	5 second
Power Source	DC 3.7V d.c. li-ion 250mAh	DC 3.3V (Powered by iOS device connected to the meter)
Battery Life	N/A	N/A
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-1000I Test Strip	AGS-1000I Test Strip
Sample Volume	Minimum 0.7 micro liter	Minimum 0.7 micro liter
Other function	Transmit measure data to iPhone or iPod through blue tooth. iHealth BG5L use Bluetooth 4.0 wireles radio technology; and iHealth BG5 use Bluetooth 3.0 wireles radio technology	N/A
Control solution	iHealth Control solution (Level I / II / III) The control solution is exactly the same as AG-608N control solution, only the name is different	AG-608N control solution (cleared in K110017)

8.0 Performance summary

iHealth BG5 and BG5L Wireless Smart Gluco-Monitoring System conforms to the following standards:

- ISO 15197: In vitro diagnostic test systems- Requirements for blood-glucose monitoring systems for self-testing in managing diabetes mellitus.
- IEC 61010-1 : 2001, Safety requirements for electrical equipment for

measurement,control, and laboratory use Part 1:General requirements

- EN 61326-1:2006Electrical equipment for measurement, control and laboratory use - EMC requirements part 1: General requirements
- EN 61326-2-6 Electrical equipment for measurement, control and laboratory use - EMC requirements Part 2-6: Particular requirements - In vitro diagnostic (IVD) medical equipment
- IEC 61010-2-101: 2002,Particular requirements for in vitro diagnostic (IVD) medical equipment
- CLSI EP6-A:2003,Evaluation of the Linearity of Quantitative Measurement Procedures: A Statistical Approach; Approved Guideline

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

9.0 Comparison to the predict device and the conclusion

iHealth BG5 and BG5L Wireless Smart Gluco-Monitoring System is similar with the predicate device iHealth BG3 Smart Glucose Monitoring System, they are all for single people use, they use the same test strip, and can test the blood glucose at the alternative site. The hematocrit range, the altitude and the use function are all the same. The appearance of the new devices is different, and iHealth BG5 and BG5L meter obtain LED display on the devices, and can complete the measurement function themselves. Moreover, the new device BG5 and BG5L can connect to an iPone, iPod touch or iPad to display measurement results through Bluetooth.

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
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

April 12, 2013

Andon Medical Co., Ltd.
C/O Yi Liu
NO. 26 HANGYU ROAD
TIANJIN AIRPORT ECONOMIC AREA
TIANJIN, CHINA 300381

Re: K123935
Trade/Device Name: iHealth BG5 Wireless Smart Gluco-Monitoring System
iHealth BG5L Wireless Smart Gluco-Monitoring System
Regulation Number: 21 CFR 862.1345
Regulation Name: Glucose test system
Regulatory Class: II
Product Code: NBW, CGA, JQP, JJX
Dated: March 08, 2013
Received: March 12, 2013

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 Part 801); 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 regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 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/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Carol C. Benson -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

Indication for Use

510(k) Number (if known): K123935

Device Name: iHealth BG5 Wireless Smart Gluco-Monitoring System

Indications For Use:

iHealth BG5 wireless Smart Gluco-Monitoring System is intended to be used for:

- quantitative measurement of glucose in fresh capillary whole blood samples drawn from the fingertip, palm, forearm, upper arm, calf or thigh
- single person measurement only and should not be shared
- 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

iHealth BG5 wireless Smart Gluco-Monitoring System should not be used for the diagnosis of or screening for diabetes, or for neonatal use.

Alternative Site Testing (AST) should be done only during steady state times when glucose levels are not changing rapidly.

The AGS1000I test strips are intended for use with the iHealth BG5 meter to quantitatively measure glucose in fresh capillary whole blood samples drawn from the fingertips, palm, forearm, upper arm, calf or thigh using the iHealth BG5 meter.

The iHealth control solutions are intended for use with the iHealth BG5 Blood Glucose Monitoring System, to check that the glucose meter and test strips are working properly. These solutions contain a known range of glucose, as indicated on the bottles.

The iHealth Gluco-Smart App is an iOS app for iPhone, iTouch, and iPad and is used for data extraction and analysis in iHealth BG5 and BG5L Wireless Smart Gluco-Monitoring System.

Prescription Use √	And/Or	Over-The-Counter Use √
(21 CFR Part 801 Subpart D)		(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 Devices and Radiologic Health (OIR)

Yung W. Chan -S

Division Sign-Off
Office of In Vitro Devices and Radiologic Health

510(k) k123935

Indication for Use

510(k) Number (if known): K123935

Device Name: iHealth BG5L Wireless Smart Gluco-Monitoring System

Indications For Use:

iHealth BG5L wireless Smart Gluco-Monitoring System is intended to be used for:

- quantitative measurement of glucose in fresh capillary whole blood samples drawn from the fingertip, palm, forearm, upper arm, calf or thigh
- single person measurement only and should not be shared
- 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

iHealth BG5L wireless Smart Gluco-Monitoring System should not be used for the diagnosis of or screening for diabetes, or for neonatal use.

Alternative Site Testing (AST) should be done only during steady state times when glucose levels are not changing rapidly.

The AGS1000I test strips are intended for use with the iHealth BG5 meter to quantitatively measure glucose in fresh capillary whole blood samples drawn from the fingertips, palm, forearm, upper arm, calf or thigh using the iHealth BG5L meter.

The iHealth control solutions are intended for use with the iHealth BG5L Blood Glucose Monitoring System, to check that the glucose meter and test strips are working properly. These solutions contain a known range of glucose, as indicated on the bottles.

The iHealth Gluco-Smart App is an iOS app for iPhone, iTouch, and iPad and is used for data extraction and analysis in iHealth BG5 and BG5L Wireless Smart Gluco-Monitoring System.

Prescription Use √	And/Or	Over-The-Counter Use √
(21 CFR Part 801 Subpart D)		(21 CFR Part 801 Subpart C)

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