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

Re: K170231  
Trade/Device Name: iHealth Align Gluco-monitoring System (BG1);  
iHealth Wireless Smart Gluco-Monitoring System (BG5)  
Regulation Number: 21 CFR 862.1345  
Regulation Name: Glucose test system  
Regulatory Class: II  
Product Code: NBW  
Dated: August 14, 2017  
Received: August 16, 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
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,

Kellie B. Kelm -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
Indications for Use

Device Name
iHealth® Align Gluco-Monitoring System (BG1)
iHealth® Wireless Smart Gluco-Monitoring System (BG5)

Indications for Use (Describe)

The iHealth® Align Gluco-Monitoring System (BG1) consists of the iHealth® Align Glucose meter (BG1), iHealth® Blood Glucose Test Strips (EGS-2003), and the iHealth® Gluco-Smart App mobile application as the display component of the iHealth® Align Gluco-Monitoring System. The iHealth® Align Gluco-Monitoring System is intended to be used for the quantitative measurement of glucose (sugar) in fresh capillary whole blood samples drawn from the fingertip, palm, forearm, upper arm, calf, or thigh. The iHealth® Align Gluco-Monitoring System is intended to be used by a single person and should not be shared.

The iHealth® Align Gluco-Monitoring System (BG1) 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 iHealth® Align Gluco-Monitoring System should not be used for the diagnosis of or screening of diabetes or for neonatal use. Alternative site testing should be done only during steady-state times (when glucose is not changing rapidly).

The iHealth® Wireless Smart Gluco-Monitoring System (BG5) consists of the iHealth® Wireless Glucose meter (BG5), iHealth® Blood Glucose Test Strips (EGS-2003), and the iHealth® Gluco-Smart App mobile application. The iHealth® Wireless Smart Gluco-Monitoring System is intended to be used for the quantitative measurement of glucose (sugar) in fresh capillary whole blood samples drawn from the fingertip, palm, forearm, upper arm, calf, or thigh. The iHealth® Wireless Gluco-Monitoring System is intended to be used by a single person and should not be shared.

The iHealth® Wireless Smart Gluco-Monitoring System (BG5) 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 iHealth® Wireless Smart Gluco-Monitoring System should not be used for the diagnosis of or screening of diabetes or for neonatal use. Alternative site testing should be done only during steady-state times (when glucose is not changing rapidly).

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.

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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.”
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: 9/14/2017

2.0 Device information

Trade name: iHealth® Align Gluco-Monitoring system (BG1)
iHealth® Wireless Smart Gluco-Monitoring System (BG5)
Common name: Blood Glucose Monitoring System
Classification name: Blood Glucose Monitoring System

3.0 Classification

<table>
<thead>
<tr>
<th>Product code</th>
<th>classification</th>
<th>Regulation section</th>
<th>Panel</th>
</tr>
</thead>
<tbody>
<tr>
<td>NBW</td>
<td>II</td>
<td>862.1345</td>
<td>Chemistry(75)</td>
</tr>
</tbody>
</table>

4.0 Predicate device information

Manufacturer: Andon Health Co., Ltd.
Device: iHealth® BG5/BG5L WIRELESS SMART GLUCOSE MONITORING SYSTEM
510(k) number: K153278
5.0 Test principle

The blood glucose Monitoring System 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. For EGS-2003 test strip, the reactive enzyme is glucose dehydrogenase.

Capillary action at the end of the test strip draws the blood into the action chamber and the glucose in blood will take electrochemical reaction with the enzyme, the blood glucose result is displayed in 5 seconds.

6.0 Device description

The iHealth® Align Gluco-Monitoring system(BG1) consist of BG1 glucose meter, EGS-2003 test strip, iHealth® control solution(Level I, Level II, Level III), lancet and lancing device. The BG1 glucose meter can be connected to iOS device and Android device through earphone jack, and display test result on iOS or Android device.

The iHealth® wireless Smart Gluco-Monitoring System(BG5) consist of BG5 glucose meter, EGS-2003 test strip, iHealth® control solution(Level I, Level II, Level III), lancet and lancing device. The BG5 glucose meter can display test result on meter itself, and can also be connected to iOS device and Android device through bluetooth and display test result on iOS or Android device.

7.0 Intended use

For BG1

The iHealth® Align Gluco-Monitoring System(BG1) consists of the iHealth® Align Glucose meter (BG1), iHealth® Blood Glucose Test Strips (EGS-2003), and the iHealth® Gluco-Smart App mobile application as the display component of the iHealth® Align Gluco-Monitoring System. The iHealth® Align Gluco-Monitoring System is intended to be used for the quantitative measurement of glucose (sugar) in fresh capillary whole blood samples drawn from the fingertip, palm, forearm, upper arm, calf, or thigh. The iHealth® Align Gluco-Monitoring System is intended to be used by a single person and should not be shared.
The iHealth® Align Gluco-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 iHealth® Align Gluco-Monitoring System should not be used for the diagnosis of or screening of diabetes or for neonatal use. Alternative site testing should be done only during steady-state times (when glucose is not changing rapidly).

For BG5

The iHealth® Wireless Smart Gluco-Monitoring System (BG5) consists of the iHealth® Wireless Glucose meter (BG5), iHealth® Blood Glucose Test Strips (EGS-2003), and the iHealth® Gluco-Smart App mobile application. The iHealth® Wireless Smart Gluco-Monitoring System is intended to be used for the quantitative measurement of glucose (sugar) in fresh capillary whole blood samples drawn from the fingertip, palm, forearm, upper arm, calf, or thigh. The iHealth® Wireless Gluco-Monitoring System is intended to be used by a single person and should not be shared.

The iHealth® Wireless Smart Gluco-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 iHealth® Wireless Smart Gluco-Monitoring System should not be used for the diagnosis of or screening of diabetes or for neonatal use. Alternative site testing should be done only during steady-state times (when glucose is not changing rapidly).

8.0 Summary comparing technological characteristics with predicate device

Specification Comparison

<table>
<thead>
<tr>
<th>CHARACTERISTICS</th>
<th>PREDICATE</th>
<th>NEW DEVICE:</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>BG5 BGMS (K153278)</td>
<td>BG1 BGMS</td>
</tr>
<tr>
<td>Detection Method</td>
<td>Amperometry</td>
<td>Same as predicate</td>
</tr>
<tr>
<td>Enzyme</td>
<td>Glucose Oxidase</td>
<td>Glucose Oxidase and Glucose dehydrogenase</td>
</tr>
<tr>
<td>Type of Meter</td>
<td>Biosensor (Electrode)</td>
<td>Same as predicate</td>
</tr>
<tr>
<td>Sample Source</td>
<td>Capillary whole blood from AST(Alternative site testing) and finger</td>
<td>Same as predicate</td>
</tr>
<tr>
<td>---------------</td>
<td>-------------------------------------------------</td>
<td>----------------</td>
</tr>
<tr>
<td>Sample Application</td>
<td>Blood sample is placed directly to the test strip after finger or AST is lanced.</td>
<td>Same as predicate</td>
</tr>
<tr>
<td>Hematocrit Range</td>
<td>20-60%</td>
<td>Same as predicate</td>
</tr>
<tr>
<td>Operating Temperature Range</td>
<td>10°C～35°C(50°-95°F)</td>
<td>Same as predicate</td>
</tr>
<tr>
<td>Dimensions</td>
<td>9mm × 34.5mm ×19mm</td>
<td>52mm×30mm×9.5mm</td>
</tr>
<tr>
<td>Display</td>
<td>Connect to iOS device and android device to display measurement results Display on the meter</td>
<td>Connect to iOS device and android device to display measurement results</td>
</tr>
<tr>
<td>Result Presentation</td>
<td>mg/dL or mmol/L</td>
<td>mg/dL or mmol/L</td>
</tr>
<tr>
<td>Memory Capabilities</td>
<td>500 times with time and date displaying</td>
<td>1000 times with time and date displaying</td>
</tr>
<tr>
<td>Test Start</td>
<td>Automatic</td>
<td>Automatic</td>
</tr>
<tr>
<td>Test Time</td>
<td>5 second</td>
<td>5 second</td>
</tr>
<tr>
<td>Power Source</td>
<td>DC 3.7V d.c. li-ion 250mAh</td>
<td>DC3.0V (CR1620)</td>
</tr>
<tr>
<td>Battery Life</td>
<td>N/A</td>
<td>N/A</td>
</tr>
<tr>
<td>Measurement Range</td>
<td>20mg/dL-600mg/dL (1.1mmol/L~33.3mmol/L)</td>
<td>20mg/dL-600mg/dL (1.1mmol/L~33.3mmol/L)</td>
</tr>
<tr>
<td>Qualified Test Strip</td>
<td>AGS-1000I Test Strip</td>
<td>EGS-2003 and AGS-1000I Test Strip</td>
</tr>
<tr>
<td>Sample Volume</td>
<td>Minimum 0.7 micro liter</td>
<td>Minimum 0.7 micro liter</td>
</tr>
<tr>
<td>Connect Method</td>
<td>Connect to iOS device and Android device</td>
<td>Connect to iOS device and Android</td>
</tr>
</tbody>
</table>
Discussion of Non-Clinical Tests Performed

• Performance, functionality, and reliability of the proposed device has been evaluated. The performance evaluation include precision, altitude, temperature & humidity, linearity, interference, sample volume and hematocrit.

• Software: documentation was prepared and submitted for a moderate level of concern device in accordance with FDA's Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices;

Discussion of Clinical Tests Performed

User Evaluation study include a total 350 participants was completed for the iHealth® Wireless Smart Gluco-Monitoring System (BG5) and iHealth® Align Gluco-Monitoring System(BG1). The study results demonstrate that the user accuracy and ease of use (via participant questionnaire scoring) confirmed the proposed device to be substantially equivalent to the predicate device.
9.0 Comparison to the predicate device and the conclusion

The proposed device is similar with the predicate device, they are both for single patient use, can test the blood glucose at the alternative site. The hematocrit range, the altitude and the use function are all the same, and all the proposed device can be connected to not only the iOS device, but also the Android device. The only difference is the new device added new test strips.

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