



INFOPIA CO., LTD.  
C/O PRISCILLA CHUNG  
LK CONSULTING GROUP  
800 ROOSEVELT STE 417  
IRVINE CA 92620

September 28, 2016

Re: K160365

Trade/Device Name: BLE Smart Blood Glucose Monitoring System,  
BLE Smart Professional Blood Glucose Monitoring System

Regulation Number: 21 CFR 862.1345

Regulation Name: Glucose test system

Regulatory Class: II

Product Code: NBW, LFR, JJX

Dated: August 31, 2016

Received: September 2, 2016

Dear Priscilla Chung:

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

## Indications for Use

510(k) Number (if known)

K160365

Device Name

BLE Smart Professional Blood Glucose Monitoring System

Indications for Use (Describe)

The BLE Smart Professional Blood Glucose Monitoring System is intended for the quantitative measurement of glucose in capillary whole blood from the fingertips, ventral palm, dorsal hand, upper arm, forearm, calf and thigh and in venous whole blood.

The BLE Smart Professional 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 diabetes control program. This system should only be used with auto-disabling, single-use lancing devices. The BLE Smart Professional Blood Glucose 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 BLE Smart Professional Blood Glucose Test Strips are for use with the BLE Smart Professional Meter to quantitatively measure glucose in venous whole blood samples and fresh capillary whole blood samples drawn from the fingertips, ventral palm, dorsal hand, upper arm, forearm, calf and/or thigh.

The BLE Smart Professional Blood Glucose Control Solutions are for use with the BLE Smart Professional Blood Glucose Monitoring System to check that the meter and test strips are working together properly and that the test is performing correctly.

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:

Department of Health and Human Services  
Food and Drug Administration  
Office of Chief Information Officer  
Paperwork Reduction Act (PRA) Staff  
[PRASStaff@fda.hhs.gov](mailto:PRASStaff@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.”*

## Indications for Use

510(k) Number (if known)

K160365

Device Name

BLE Smart Blood Glucose Monitoring System

Indications for Use (Describe)

The BLE Smart Blood Glucose Monitoring System is intended for the quantitative measurement of glucose (sugar) in fresh capillary whole blood from the fingertips, ventral palm, dorsal hand, upper arm, forearm, calf and thigh. The BLE Smart Blood Glucose Monitoring System is intended to be used by a single patient and should not be shared.

The BLE Smart Blood Glucose Monitoring System is intended for testing outside the body (in vitro diagnostic use) by people with diabetes at home as an aid to monitor the effectiveness of diabetes control. It 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 BLE Smart Blood Glucose Test Strips are for use with the BLE Smart Meter to quantitatively measure glucose in fresh capillary whole blood. Fresh capillary whole blood samples may be drawn from the fingertips, ventral palm, dorsal hand, upper arm, forearm, calf and thigh.

The BLE Smart Blood Glucose Control Solutions are for use with the BLE Smart Blood Glucose Monitoring System to check that the meter and test strips are working together properly and the test is performing correctly.

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**  
(K160365)

This summary of 510(K) information is being submitted in accordance with requirements of 21 CFR Part 807.92.

Date: 08/31/2016

**1. Applicant / Submitter:**

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**2. Submission Correspondent:**

Priscilla Chung  
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**3. Device:**

- **Trade Name:**  
BLE Smart Blood Glucose Monitoring System  
BLE Smart Professional Blood Glucose Monitoring System
- **Classification Name:**  
Blood Glucose Test System
- **Classification regulation:**  
21 CFR Part 862.1345, 21 CFR Part 862.1660
- **Product Code:**  
NBW, LFR, JJX

**4. Predicate Device:**

K130181, GluNEO™ Blood Glucose Monitoring System & GluNEO™ Professional Blood Glucose Monitoring System by Infopia Co., Ltd.

**5. Description:**

BLE Smart Blood Glucose Monitoring System / BLE Smart Professional Blood Glucose Monitoring System consist of a meter, test strips, and control solutions (Level 1, Level 2 and level 3). These blood glucose test systems are an in vitro diagnostic device designed for measuring the concentration of glucose in blood by means of an electrical current produced in the test strip and sent to the meter for measurement.

## **6. Indications for use:**

### **BLE Smart Blood Glucose Monitoring System**

The BLE Smart Blood Glucose Monitoring System is intended for the quantitative measurement of glucose (sugar) in fresh capillary whole blood from the fingertips, ventral palm, dorsal hand, upper arm, forearm, calf and thigh. The BLE Smart Blood Glucose Monitoring System is intended to be used by a single patient and should not be shared. The BLE Smart Blood Glucose Monitoring System is intended for testing outside the body (in vitro diagnostic use) by people with diabetes at home as an aid to monitor the effectiveness of diabetes control. It 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 BLE Smart Blood Glucose Test Strips are for use with the BLE Smart Meter to quantitatively measure glucose in fresh capillary whole blood. Fresh capillary whole blood samples may be drawn from the fingertips, ventral palm, dorsal hand, upper arm, forearm, calf and thigh.

The BLE Smart Blood Glucose Control Solutions are for use with the BLE Smart Blood Glucose Monitoring System to check that the meter and test strips are working together properly and the test is performing correctly.

### **BLE Smart Professional Blood Glucose Monitoring System**

The BLE Smart Professional Blood Glucose Monitoring System is intended for the quantitative measurement of glucose in capillary whole blood from the fingertips, ventral palm, dorsal hand, upper arm, forearm, calf and thigh and in venous whole blood. The BLE Smart Professional 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 diabetes control program. This system should only be used with auto-disabling, single-use lancing devices. The BLE Smart Professional Blood Glucose 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 BLE Smart Professional Blood Glucose Test Strips are for use with the BLE Smart Professional Meter to quantitatively measure glucose in venous whole blood samples and fresh capillary whole blood samples drawn from the fingertips, ventral palm, dorsal hand, upper arm, forearm, calf and/or thigh.

The BLE Smart Professional Blood Glucose Control Solutions are for use with the BLE Smart Professional Blood Glucose Monitoring System to check that the meter and test strips are working together properly and that the test is performing correctly.

## **7. Comparison to the Cleared Device**

The modifications are as below.

- **Adding Bluetooth Function**

Bluetooth wireless technology is added to the BLE SmartMeter. The meter can communicate with smart devices such as a smart phone or a tablet via MyHealthPoint Listener App. The app directly allows the data to upload readings on MyHealthPoint Portal (K132930). The unmodified device (K130181) already had the data transfer function of transmitting the stored information (data) to PC via a USB cable.

The following modifications occurred due to adding Bluetooth module.

**Infopia Co., Ltd. Blood Glucose Monitoring System**  
Special 510(k) for In Vitro Diagnostic Device

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- Adding Bluetooth module chip
- Modifications to hardware components and re-layout of PCB
- Changes to Firmware
  
- **Appearance of the BLE Smart Meter**
  - The color and the texture of the meter housings have been changed.
  - The raw material of LCD Screen has been changed from PMMA to PET FLIM.
  - The texture of some parts (LCD Screen, Power button, Up/Down button, Back Case, Bottom Case, Battery cover) has been changed to Non-Etched (Gloss).
  - The color of deco also has been changed from orange to bluish-green per buyer (distributor)'s request.
  
- **Device Name Change**

The device name has changed from GluNEO™ Blood Glucose Monitoring System and GluNEO™ Professional Blood Glucose Monitoring System to BLE Smart Blood Glucose Monitoring System and BLE Smart Professional Blood Glucose Monitoring System.

Other than these modifications, the modified meter has the following similarities to the cleared device:

- has the same intended use,
- uses the same operating principle,
- adopts the same use environment and calibration method.

## 8. Performance Data

Non-clinical: Verification, validation and testing activities were conducted to establish the performance, functionality and reliability characteristics of the modified devices. The device passed all of the tests based on pre-determined Pass/Fail criteria.

Disinfection Study: Disinfectant CaviWipes with the EPA registration number of 46781-8 has been validated demonstrating complete inactivation of live virus of use with the meter.

## 9. Conclusion

The conclusion drawn from the verification/validation activities is that the subject devices is substantially equivalent to the predicated device.