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

August 26, 2015

INFOPIA CO., LTD.
C/O PRISCILLA CHUNG
REGULATORY AFFAIRS CONSULTANT
2651 E CHAPMAN AVE STE 110
FULLERTON CA 92833

Re: K150274
Trade/Device Name: GDH Professional Blood Glucose Monitoring System
GDH Professional LED Blood Glucose Monitoring System
Regulation Number: 21 CFR 862.1345
Regulation Name: Glucose test system
Regulatory Class: II
Product Code: NBW, LFR, JJX
Dated: July 22, 2015
Received: July 27, 2015

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

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K150274

Device Name
GDH Professional LED Blood Glucose Monitoring System

Indications for Use *(Describe)*
The GDH Professional LED 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 venous whole blood. The GDH Professional LED 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 GDH Professional LED Blood Glucose Monitoring System should not be used for the diagnosis of or screening of diabetes and/or for neonatal use. Alternative site testing should be done only during steady – state times (when glucose is not changing rapidly).

The GDH Professional test strips are for use with the GDH Professional LED meter to quantitatively measure glucose (sugar) 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 GDH Professional control solutions are for use with the GDH Professional LED meter and GDH Professional test strips 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
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."

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K150274

Device Name
GDH Professional Blood Glucose Monitoring System

Indications for Use *(Describe)*
The GDH 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 venous whole blood. The GDH 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 GDH Professional Blood Glucose Monitoring System should not be used for the diagnosis of or screening of diabetes and/or for neonatal use. Alternative site testing should be done only during steady – state times (when glucose is not changing rapidly).

The GDH Professional test strips are for use with the GDH Professional meter to quantitatively measure glucose (sugar) 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 GDH Professional control solutions are for use with the GDH Professional meter and GDH Professional test strips 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
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
(K150274)

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

Date: 08/24/2015

1. **Applicant / Submitter:**

   Infopia Co., Ltd.
   132, Anyangcheondong-ro, Dongan-gu,
   Anyang, Gyeonggi-do,
   Republic of Korea 431-836
   Tel : +82-31-460-0415 Fax : +82-31-460-0403

2. **Submission Correspondent:**

   Priscilla Chung
   LK Consulting Group USA, Inc.
   2651 E Chapman Ave. Ste 110,
   Fullerton, CA 92831
   Phone: 714-202-5789 Fax: 714-409-3357
   Email: juhee.c@lkconsultinggroup.com

3. **Device:**

   - **Trade Name:**
     GDH Professional Blood Glucose Monitoring System
     GDH Professional LED Blood Glucose Monitoring System
   - **Classification Name:**
     Glucose test system, Quality control material (assayed and unassayed)
   - **Classification regulation:**
     21 CFR Part 862.1345, 21 CFR Part 862.1660
   - **Product Code:**
     NBW, LFR, JJX

4. **Predicate Device:**

   GluNEO™ Lite Professional Blood Glucose Monitoring System(K132966) by Infopia Co., Ltd.

5. **Description:**

   GDH Professional Blood Glucose Monitoring System and GDH Professional LED 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 in vitro diagnostic devices 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:

GDH Professional Blood Glucose Monitoring System
The GDH 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 venous whole blood. The GDH 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 GDH Professional Blood Glucose Monitoring System should not be used for the diagnosis of or screening of diabetes and/or for neonatal use. Alternative site testing should be done only during steady – state times (when glucose is not changing rapidly).

The GDH Professional test strips are for use with the GDH Professional meter to quantitatively measure glucose (sugar) 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 GDH Professional control solutions are for use with the GDH Professional meter and GDH Professional test strips to check that the meter and test strips are working together properly and that the test is performing correctly.

GDH Professional LED Blood Glucose Monitoring System
The GDH Professional LED 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 venous whole blood. The GDH Professional LED 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 GDH Professional LED Blood Glucose Monitoring System should not be used for the diagnosis of or screening of diabetes and/or for neonatal use. Alternative site testing should be done only during steady – state times (when glucose is not changing rapidly).

The GDH Professional test strips are for use with the GDH Professional LED meter to quantitatively measure glucose (sugar) 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 GDH Professional control solutions are for use with the GDH Professional LED meter and GDH Professional test strips 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 the changes in meter appearance, battery quantity, LCD display type and LED light (only for GDH Professional LED) and icon display.

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.

Robustness Study: Based on the outcome of the robustness study designed to mimic 3 years' rigorous repetition of cleaning and disinfection procedures, it is confirmed that GDH Professi onal LED System is robust in maintaining its appearance, operational functions and analytical performance.

9. Conclusion

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