July 13, 2021

Osang Healthcare Co., Ltd.
% Priscilla Chung
Regulatory Affairs Consultant
LK Consulting Group USA, Inc.
1150 Roosevelt STE 200
Irvine, California 92620

Re: K203562
Trade/Device Name: Finetest Lite Blood Glucose Monitoring System
Regulation Number: 21 CFR 862.1345
Regulation Name: Glucose Test System
Regulatory Class: Class II
Product Code: NBW
Dated: November 12, 2020
Received: December 7, 2020

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. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. 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 and Part 809); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

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 https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Marianela Perez-Torres, Ph.D.
Deputy Director
Division of Chemistry
and Toxicology Devices
OHT7: Office of In Vitro Diagnostics
and Radiological Health
Office of Product Evaluation and Quality
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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
k203562

Device Name
Finetest Lite Blood Glucose Monitoring System

Indications for Use *(Describe)*
The Finetest Lite Blood Glucose Monitoring System is comprised of Finetest Lite Blood Glucose meter and Finetest Lite Blood Glucose Testing Strips. It 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 Finetest Lite Blood Glucose Monitoring System is intended to be used by a single patient and should not be shared. The Finetest Lite 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).

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.

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510(k) Summary

(k203562)

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

Date: 5/9/2021

1. **Applicant / Submitter:**

OSANG Healthcare Co., Ltd.
132, Anyangcheondong-Ro
Dongan-Gu
Anyang, Gyeonggido, 14040, Republic of Korea
Tel : +82-31-460-0415 Fax : +82-31-460-0401

2. **Submission Correspondent:**

Priscilla Chung
LK Consulting Group USA, Inc.
1150 Roosevelt, STE 200, Irvine CA 92620
Irvine, CA 92620
Phone: 714-202-5789 Fax: 714-409-3357
Email: juhee.c@lkconsultinggroup.com

3. **Device:**

- **Trade Name:**
  Finetest Lite Blood Glucose Monitoring System
- **Classification Name:**
  Blood Glucose Test System
- **Classification regulation:**
  21 CFR Part 862.1345
- **Product Code:**
  NBW

4. **Predicate Device:**

GluNEO Lite Blood Glucose Monitoring System (K132966) by OSANG Healthcare Co., Ltd.

5. **Description:**

The proposed Finetest Lite Blood Glucose Monitoring System consists of a meter, test strips, control solution and a lancing device. This blood glucose test system is 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:

The Finetest Lite Blood Glucose Monitoring System is comprised of Finetest Lite Blood Glucose meter and Finetest Lite Blood Glucose Testing Strips. It 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 Finetest Lite Blood Glucose Monitoring System is intended to be used by a single patient and should not be shared. The Finetest Lite 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).

7. Comparison to the Cleared Device

The modifications are changes in the meter appearance, name of device/distributor, and meter memory. Other than these modifications, the modified meter is identical to the predicate device in terms of indications for use, technological characteristics, and specifications.

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.