August 29, 2022

HMD BioMedical Inc.
Chin-Hsiung Hsu
Product Manager
No. 181, Minsheng Street
Hsinchu County, 30548
Taiwan

Re: K212248
Trade/Device Name: GlucoLeader Enhance 2 Blood Glucose Monitoring System
Regulation Number: 21 CFR 862.1345
Regulation Name: Glucose Test System
Regulatory Class: Class II
Product Code: NBW
Dated: June 10, 2022
Received: June 21, 2022

Dear Chin-Hsiung Hsu:

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,

Paula Caposino, Ph.D.
Acting Deputy Director
Division of Chemistry
and Toxicology Devices
OHT7: Office of In Vitro Diagnostics
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)*
K212248

Device Name
GlucoLeader Enhance 2 Blood Glucose Monitoring System

Indications for Use *(Describe)*
The GlucoLeader Enhance 2 Blood Glucose Monitoring System is intended to be used for the quantitative measurement of glucose (sugar) in fresh capillary whole blood samples drawn from the fingertip. The GlucoLeader Enhance 2 Blood Glucose Monitoring System is comprised of the GlucoLeader Enhance 2 Blood Glucose Meter and the GlucoLeader Enhance 2 Blood Glucose Test Strips. The GlucoLeader Enhance 2 Blood Glucose Monitoring System is intended to be used by a single person and should not be shared. It is intended for self-testing outside the body (in vitro diagnostic use) by people with diabetes at home (over the counter [OTC]) as an aid to monitor the effectiveness of diabetes control. The GlucoLeader Enhance 2 Blood Glucose Monitoring System should not be used for the diagnosis of or screening for diabetes. GlucoLeader Enhance 2 Blood Glucose Monitoring System is not for use in neonates.

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

1. Submitter

HMD BioMedical Inc.

Address:	No.181, Minsheng Street., Xinpu Township, Hsinchu County 30548, Taiwan (R.O.C.)
Phone:	+886-3-589-5000
Fax:	+886-3-588-5500
Contact:	Mr. Chin-Hsiung Hsu, Product Manager
Date Prepared:	August 29, 2022

2. Identification of the Device

Proprietary/Trade name:	GlucoLeader Enhance 2 Blood Glucose Monitoring System
Model Number:	Enhance 2
Classification Product Code:	NBW
Regulation Number:	862.1345
Regulation Description:	Glucose test system
Review Panel:	Clinical Chemistry
Device Class:	II

3. Identification of the Predicate Device

Predicate Device Name:	GlucoLeader Enhance Blood Glucose Monitoring System
Manufacturer:	HMD BioMedical Inc.
Classification Product Code:	NBW
Regulation number:	862.1345
Device Class:	II
510(k) Number:	K182428

4. Device Description

The GlucoLeader Enhance 2 Blood Glucose Monitoring System is designed to pursuit the accuracy in blood glucose monitoring to provide with testing. The GlucoLeader Enhance 2 Blood Glucose Monitoring System mainly consists of four parts as below,

(1) GlucoLeader Enhance 2 Blood Glucose Meter
(2) GlucoLeader Enhance 2 Blood Glucose Test Strips*
(3) Glucose Control Solutions (L1, L2)*
(4) Check Strip*.

* These products are intended to be used together to get accurate blood glucose test results. They are not included in the kit package, and should be purchased separately.

Display screen size of the meter is 1.73" x 1.7", and weight of the meter is 0.122 lbs (55.2 grams). The GlucoLeader Enhance 2 Blood Glucose Monitoring System is traceable to the NIST (SRM) 917A. The GlucoLeader Enhance Glucose Control Solutions have L1 and L2 levels for optional purchasing.

The GlucoLeader Enhance 2 Blood Glucose Test Strips have been updated with Glucose dehydrogenase-FAD Enzyme, which not only improves the accuracy of measurements, but also increases the HCT interference range up to 10-70%. Also, the required test blood sample volume is reduced to 0.8 μL, and the test reaction time is only 5 seconds.

If the GlucoLeader Enhance 2 Blood Glucose Meter is being operated by a second person who is providing testing assistance to the user, the meter and lancing device should be disinfected prior to use by the second person. Consult your healthcare professional if unusual readings occur.

5. Intended Use/ Indications for Use of the Device

The GlucoLeader Enhance 2 Blood Glucose Monitoring System is intended to be used for the quantitative measurement of glucose (sugar) in fresh capillary whole blood samples drawn from the fingertip. The GlucoLeader Enhance 2

Blood Glucose Monitoring System is comprised of the GlucoLeader Enhance 2 Blood Glucose Meter and the GlucoLeader Enhance 2 Blood Glucose Test Strips. The GlucoLeader Enhance 2 Blood Glucose Monitoring System is intended to be used by a single person and should not be shared. It is intended for self-testing outside the body (in vitro diagnostic use) by people with diabetes at home (over the counter [OTC]) as an aid to monitor the effectiveness of diabetes control. The GlucoLeader Enhance 2 Blood Glucose Monitoring System should not be used for the diagnosis of or screening for diabetes. GlucoLeader Enhance 2 Blood Glucose Monitoring System is not for use in neonates.

6. Comparison of Differences and Substantial Equivalence Determination

The GlucoLeader Enhance 2 submitted in this 510(k) file is substantially equivalent in intended use, design, technology/principles of operation, materials and performance to the cleared GlucoLeader Enhance (K182428). Differences between the devices cited in the following do not raise any new issue of substantial equivalence.

Feature	Subject device K212248	Predicate device K182428	SE determination
Meter Appearance	 Green color	 Blue color	***Equivalent*** Although the shell colors of the subject device and the predicate device are different, but their materials (PMMA) are the same, and the differences between these devices does not raise new issue of substantial equivalence.
Methodology	Amperometry glucose biosensor	Amperometry glucose biosensor	***Same***
Meter Dimension	3.81 in(L) × 2.36 in (W) × 0.65in (H)	3.81 in(L) × 2.36 in (W) × 0.65in (H)	***Same***

Feature	Subject device	Predicate device	SE determination
	K212248	K182428	
Measuring Range	10 to 600 mg/dL (0.6 to 33.3 mmol/L)	10 to 600 mg/dL (0.6 to 33.3 mmol/L)	***Same***
Resolution	1 mg/dL LCD display	1 mg/dL LCD display	***Same***
Reaction Time	5 seconds	5 seconds	***Same***
Operating Environment	8-44˚C, 10-90% R.H.	8-44˚C, 10-90% R.H.	***Same***
Storage Environment	-25-70˚C, 10-90% R.H.	-25-70˚C, 10-90% R.H.	***Same***
Power Source	One parallel connected lithium batteries (3V, CR2032)	One parallel connected lithium batteries (3V, CR2032)	***Same***
Battery Operation Life	More than 1000 times test	More than 1000 times test	***Same***
Data memory/Recall	Storage 800 test results	Storage 800 test results	***Same***
Labeling	Model: Enhance 2; Rename the test strip: GlucoLeader Enhance 2 Test Strips	Model: Enhance	***Different*** Different in product model and strip name. However, it does not affect the intended use or alter the fundamental scientific technology of subject device.
PCB layout	Add BLE module	No BLE Module	***Different*** The change is the addition of a BLE module on the PCBA. However, it does not affect the intended use or alter the fundamental scientific technology of subject device.
Wireless communication	Bluetooth Low Energy V4.0 (optional)	N/A	***Different*** The device is only allowed to complete the pairing connection and send data after the blood glucose test is completed or the

Feature	Subject device	Predicate device	SE determination
	K212248	K182428	
			connection mode is turned on. The transmission is under the authorization of the user. However, it does not affect the intended use or alter the fundamental scientific technology of subject device.

7. Non-clinical Testing

The GlucoLeader Enhance 2 has been compared with "GlucoLeader Enhance (K182428)" according to the above table. The subject device has same intended use, principle of operation as the predicate device. We have completed the design control process and the validation tests to confirm the safety and performance of subject device. This change was for:

1. The color of the meter appearance changed from blue to green.
2. Rename the test strip which is dedicated to Enhance 2 system.
3. Add the Bluetooth function to the meter, changes including PCB layout, firmware for BLE pairing and transmission, and wireless communication.

After the risk management process, GlucoLeader Enhance 2 was validated. The verification and validation activities are summarized as below.

- Software validation and wireless security, including SweynTooth vulnerabilities and cybersecurity evaluation, complied with Guidance on software validation, wireless technology and cybersecurity.
- Electromagnetic compatibility (EMC), conducted and complied with IEC 60601-1-2.

After testing, it guarantees the security of data transmission will not be interfered by other products with BLE, and can transmit multiple data at the same time. All data are correct, and they prove the reliability and accuracy of the GlucoLeader Enhance 2.

8. Clinical Testing

No new clinical test data was used to support the decision of substantial equivalence.

9. Conclusion

The new version of the GlucoLeader Enhance 2 Blood Glucose Meter has a green color appearance and is equipped with a BLE Bluetooth module for wireless transmission, not relating to the effectiveness and accuracy aspects. The new version of the GlucoLeader Enhance 2 Blood Glucose Meter can be used directly with the GlucoLeader Enhance 2 Blood Glucose Test Strip without any difference.

Although there are some specifications that are different between subject device and predicate device (K182428), the test results complied with the test requests, and this demonstrates that the differences between these parameters would not impact the safety and effectiveness of the subject device. Therefore, the difference between the subject device and the predicate device did not raise any problem of substantial equivalence. The subject device is substantially equivalent to the predicate device in intended use, safety and performance claims.

The conclusions drawn from the non-clinical & clinical tests demonstrate that the device is as safe, as effective, and performs as well as the legally marketed device identified in the submission. Thus, the subject device is substantially equivalent to the predicate device.