November 1, 2019

EPS Bio Technology Corp.
RF Jain
No. 8 R&D RD.III Hsinchu Science Park
Hsinchu, 30077
Taiwan

Re: K190189
Trade/Device Name: MDT2 BLE Self-Monitoring Blood Glucose System
Regulation Number: 21 CFR 862.1345
Regulation Name: Glucose test system
Regulatory Class: Class II
Product Code: NBW
Dated: October 1, 2019
Received: October 2, 2019

Dear RF Jain:

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,

Kellie B. Kelm, Ph.D.
Acting 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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
k190189

Device Name
MDT2 BLE Self Monitoring Blood Glucose system

Indications for Use *(Describe)*
The MDT2 BLE Self Monitoring Blood Glucose System is intended for the quantitative measurement of glucose in fresh capillary whole blood from fingertip, palm, or forearm. Testing is done outside the body (In Vitro diagnostic use). It is indicated for use at home (over the counter [OTC]) by a single patient with diabetes and should not be shared, as an aid to monitor the effectiveness of diabetes control. The system is not to be used on neonates, nor for the diagnosis of, or screening for diabetes mellitus. Alternative site testing can be only used during steady-state blood glucose conditions.

The system consists of the MDT2 BLE meter and the MDT2 BLE test strips. The MDT2 BLE meter only is used with the MDT2 BLE test strips to quantitatively measure glucose in fresh capillary whole blood from fingertip, palm, or forearm.

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.

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510(K) Summary of MDT2 BLE Self-monitoring Blood Glucose System (As required by 21 CFR 807.92)

September 30, 2019

Type of 510(k): Special 510(k) k190189

Submitter Information

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Device Name

Proprietary Name:	MDT2 BLE Self-Monitoring Blood Glucose System
Common Name:	Blood Glucose Test System
Product Code:	NBW
Classification Name	Blood Glucose Test System, Over-the Counter
Classification:	Class II
Regulation Number:	21 CFR 862.1345

Predicate Device

Proprietary Name:	EM40 Self-Monitoring Blood Glucose System
510(k) Number:	K133389

Device Description

The modified device of MDT2 BLE glucose meter is derived from the existing device of EM40 glucose meter and the modified device contain the Bluetooth function to transfer glucose results to the mobile app.

The self-monitoring blood glucose system consists of a blood glucose meter and test strips which are designed, tested, and verified to work together as a system to produce accurate blood glucose test results.

The electrochemical principle on the test strip is the reaction of FAD glucose dehydrogenase (FAD-GDH) with blood glucose and a small electrical current generated proportional to the glucose concentration in the blood sample. The meter measures the current and displays the blood glucose result.

Intended Use

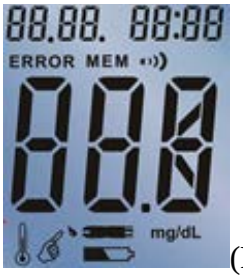
The MDT2 BLE Self-Monitoring Blood Glucose System is intended for the

quantitative measurement of glucose in fresh capillary whole blood from fingertip, palm, or forearm. Testing is done outside the body (In Vitro diagnostic use). It is indicated for use at home (over the counter [OTC]) by a single patient with diabetes and should not be shared, as an aid to monitor the effectiveness of diabetes control. The system is not to be used on neonates, nor for the diagnosis of, or screening for diabetes mellitus. Alternative site testing can be only used during steady-state blood glucose conditions.

The system consists of the MDT2 BLE meter and the MDT2 BLE test strips. The MDT2 BLE meter only is used with the MDT2 BLE test strips to quantitatively measure glucose in fresh capillary whole blood from fingertip, palm, or forearm.

Comparison to the Predicate

Similarities and Differences		
Item	**Predicate Device**	**Modified Device**
Name	EM40 K133389	MDT2 BLE
Intended use	EM40 Self-Monitoring Blood Glucose System is intended for the quantitative measurement of glucose in fresh capillary whole blood from fingertip, palm, or forearm. Testing is done outside the body (In Vitro diagnostic use). It is indicated for use at home (over the counter [OTC]) by a single patient with diabetes and should not be shared, as an aid to monitor the effectiveness of diabetes control. The system is not to be used on neonates, nor for the diagnosis of, or screening for diabetes mellitus. Alternative site testing can be only used during steady-state blood glucose conditions.	Same as predicate
Sample type	Fresh capillary whole blood	Same as predicate
Sample site	Finger, palm or forearm.	Same as predicate
Sample Volume	0.6 uL	Same as predicate
Reaction Time	5 seconds	Same as predicate
Measuring Range	20-600 mg/dL	Same as predicate
Hematocrit Range	20-60%	Same as predicate

Operating condition	50-104°F(10-40°C) <90 % RH	Same as predicate
Storage Condition	35.6-86°F(2-30°C) 40-85% RH	Same as predicate
Detection method	Electrochemical biosensor technique	Same as predicate
Enzyme	FAD glucose dehydrogenase	Same as predicate
Mediator	Potassium ferricyanide	Same as predicate
Coding	No code	Same as predicate
Memory Capacity	480 tests	Same as predicate
Measurement Unit	mg/dL	Same as predicate
Memory Setting	Review 480 results	Same as predicate
Power Supply	CR2032 3V *2	Same as predicate
Battery Life	Over 2000 tests	Same as predicate
Meter Case material	Polycarbonate (PC)	Same as predicate
Meter Case Texture	Non-Textured Surface	Same as predicate
Meter shape	Oval shape	Rectangle shape
Meter color	Black	White
Button	One Front button and two side buttons	Two front buttons
Meter Dimension	86 x 47 x 13.8 mm	98 x 49.9 x 11.3 mm
Weight	43 grams w/o batteries	49 grams w/o batteries
LCD Dimension	43.0 x 35.0 mm	55.7 x 36.7 mm
Display icons	 (Real Photo)	 (Drawing)
Strip Insert location	Upper meter	Lower meter
Pin assignment of Test strip electrode		
Memory mode	Average on 7/14/30/90 days	No average

Measurement Mode	Test Mode and Control Solution Mode	Test Mode (before meal, after meal) and Control Solution Mode
Reset function	N/A	Yes
Bluetooth	N/A	Yes

In comparison with the predicate device, the modifications of the proposed device are as below:

1. Change the product name.
2. Meter outlook change with shape, color, meter buttons, dimension, weight and LCD dimension, the same LCD type with different display icons, and the insert location of test strip.
3. Change the electrode pin assignment of test strip.
4. Software(firmware) changes with meter functions: memory mode, measurement mode, and reset function. And, also for display icons (before meal, after meal, Control, AM, PM icon) and buttons.
5. Addition of the Bluetooth with wireless data transfer function (hardware and firmware changes) : the meter added Bluetooth can communicate with a mobile device App.

Other than the above modification, the following remains the same to the predicate device:

- Has the same intended use
- Uses the same operating principle
- Uses the same power source
- The test strips use the same glucose Enzyme and mechanism

Due to the addition of the Bluetooth with wireless data transfer function, cybersecurity also becomes a necessary item for risk control. There is a cybersecurity summary plan & report to confirm this issue.

Summary of Design Control Activities

Based on the modifications, the risk analysis was assessed, and the risks were identified and controlled with verifications and validation activities which mitigated the risk index to acceptability. The risk analysis and design control activities were summarized below:

Risk Analysis

The risk analysis was conducted according to ISO 14971:2007 standard. A Failure Modes and Effects Analysis (FMEA) was assessed to identify potential hazard and unaccepted risks for each modification. The control measures were to mitigate these risks to acceptable level with the implemented verification and validation activities. The complete analysis was in MDT2 BLE SMBGS risk management report in this submission.

Verification and Validation activities

The verification and validate (V&V) activities were conducted based on the impact of the modification and detailed in the MDT2 BLE SMBGS risk management report. The similar V&V testing with similar acceptance criteria as the predicate was performed and the design outputs met pre-determined design inputs was confirmed in the software validation report in this submission.

Conclusion

The modified device, MDT2 BLE SMBGS, has the same intended use and fundamental scientific technology as the predicate, EM40 SMBGS which received 510 (k) clearance K133389.

After conducting risk analysis and design control activities, the modified device is substantially equivalent to the predicate device.