August 24, 2018

EPS Bio Technology Corp.
Cynthia Hung
Official Correspondent
No. 8, R&D Rd. III
Hsinchu Science Park
Hsinchu, 30077
Taiwan

Re: K182057
Trade/Device Name: EasyMax BT Self-Monitoring Blood Glucose System
Regulation Number: 21 CFR 862.1345
Regulation Name: Glucose test system
Regulatory Class: Class II
Product Code: NBW
Dated: July 30, 2018
Received: July 31, 2018

Dear Cynthia Hung:

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/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/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 -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
k182057

Device Name
EasyMax BT Self Monitoring Blood Glucose system

Indications for Use *(Describe)*
The EasyMax BT 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 EasyMax BT meter and the EasyMax BT test strips. The EasyMax BT meter only is used with the EasyMax BT 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.**

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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# 510K) Summary of EasyMax BT Self-monitoring Blood Glucose System (As required by 21 CFR 807.92)

July, 16, 2018

**Type of 510(k):** Special 510(k) **510(k) number:** k182057

## Submitter Information


| | |
|---|---|
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| Contact Person: | Cynthia Hung |
| E-mail: | cynthia@epsbio.com.tw |


## Device Name

| | |
|---|---|
| Proprietary Name: | EasyMax BT 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: | EasyMax MU Self-Monitoring Blood Glucose System |
| 510(k) Number: | K121207 |

## Device Description

The modified device of EasyMax BT SMBGS is derived from the existing device of EasyMax MU SMBGS with the addition of a Bluetooth dongle on the meter.

The 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 system also includes the control solution which is used to check the performance of the system.

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.

# 510K) Summary of EasyMax BT Self-monitoring Blood Glucose System (As required by 21 CFR 807.92)

July, 16, 2018

## Intended Use

The EasyMax BT 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 EasyMax BT meter and the EasyMax BT test strips. The EasyMax BT meter only is used with the EasyMax BT 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 | EasyMax MU<br>K121207 | EasyMax BT |
| Intended use | EasyMax MU 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)<br><90 % RH | Same as predicate |
| Storage Condition | 35.6-86°F(2-30°C)<br>40-85% RH | Same as predicate |
| Detection method | Electrochemical biosensor technique | Same as predicate |
| Enzyme | FAD glucose dehydrogenase | Same as predicate |
| Mediator | Potassium Derricyanide | Same as predicate |
| Coding | No code | Same as predicate |
| Memory Capacity | 480 tests | Same as predicate |
| Measurement Unit | mg/dL | Same as predicate |
| Measurement Mode | Test Mode and Control Solution Mode | Same as predicate |
| Memory Setting | Review 480 results | Same as predicate |
| Power Supply | Alkaline battery *2 | Same as predicate |
| Battery Life | Over 2000 tests | Same as predicate |
| Button | Power, left and right buttons | Same as predicate |
| LCD Dimension | 34.0 x 42.0 mm | Same as predicate |
| Meter Dimension | 95 x 50 x 15 mm | Same as predicate |
| Weight | 39.1 grams w/o batteries | Same as predicate |
| Data Transfer | N/A | Bluetooth Dongle |
| Meter picture |  |  |

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

1. Addition of the Bluetooth dongle to the meter: wireless data transfers to a mobile device and the meter can communicate with a mobile by GlucoManager App.

2. Software(firmware) changes for Bluetooth pairing and Bluetooth transmission functions


3. Change the product name

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 meters
- Uses the same glucose test strips

## 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. The EasyMax BT SMBG system was modified with adding Bluetooth Dongle and a Failure Modes and Effects Analysis (FMEA) was assessed to identify potential hazard and unaccepted risks, like transmission/communication problems, safety issues, and operating BT function. The control measures were to mitigate these risks to acceptable level with the Safety and EMC testing, FCC testing, Software function testing and human factor study. The complete analysis was in EasyMax BT SMBGS risk management report in this submission.

**Verification and Validation activities**

| Modification | Tests | Standards & References |
|---|---|---|
| Addition of the Bluetooth dongle to the meter | Safety Test | IEC 61010-1:2010; IEC61010-2-101:2002 |
| | EMC Test | IEC 60601-1-2:2014; 61326-1:2001 |
| | FCC test | FCC Part 15 Subpart B & C |
| | Human Factor Test | IEC 62366-1:2015 |
| | Drop and Vibration Test | ISTA 2A: 2011; IEC60068-2-64: 2008 |
| Software(firmware) changes for Bluetooth pairing and Bluetooth transmission functions | Software Validation Test | IEC 62304:2006; FDA guidance Document "Guidance for the Content of Pre-market Submissions for Software Contained in Medical Devices". |
| Change product name | Readability Test | For all inserts, the accept criteria: Flesch-Kincaid grade level≦8.0 |

The verification and validate (V&V) activities were conducted based on the impact of the modification and detailed in the EasyMax BT 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, EasyMax BT SMBGS, has the same intended use and fundamental scientific technology as the predicate, EasyMax MU SMBGS which received 510 (k) clearance K121207.

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