



Food and Drug Administration  
10903 New Hampshire Avenue  
Document Control Center - WO66-G609  
Silver Spring, MD 20993-0002

February 27, 2014

EPS BIO TECHNOLOGY CORP.  
CYNTHIA HUNG  
NO.8 R&D RD III, HSINCHU SCIENCE PARK  
HSINCHU CITY, 30077  
TAIWAN

Re: K133647

Trade/Device Name: EMV3.1 Self Monitoring Blood Glucose System  
EMV3.1 Pro Blood glucose System

Regulation Number: 21 CFR 862.1345

Regulation Name: Glucose test system

Regulatory Class: II

Product Code: NBW, LFR, JJX

Dated: January 29, 2014

Received: January 30, 2014

Dear Ms. 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. 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 Small Manufacturers, International and Consumer Assistance 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" (21CFR 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 Small Manufacturers, International and Consumer Assistance 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,

**Courtney H. Lias -S**

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

**Indications for Use**

510(k) Number (if known)  
K133647

Device Name  
EMV3.1 Pro blood Glucose system

Indications for Use (Describe)

The EMV3.1 Pro Blood Glucose System is intended for the quantitative measurement of glucose in venous whole blood or fresh capillary whole blood from fingertip. Testing is done outside the body (In Vitro diagnostic use). It is intended for multiple-patient use in professional healthcare settings as an aid to monitor the effectiveness of diabetes control. The system is only used with single-use lancing devices. The system is not to be used on neonates, nor for the diagnosis of, or screening for diabetes mellitus. The system includes the speaking function but is not intended to be operated by visually impaired users.

The system consists of the EMV3.1 Pro meter and the EMV3.1 Pro test strips. The EMV3.1 Pro meter only is used with the EMV3.1 Pro test strips to quantitatively measure glucose in venous whole blood or fresh capillary whole blood from fingertip.

The EMV3.1 Glucose Control Solution

For use with the EMV3.1 Pro Blood Glucose System as a quality control check to verify the accuracy of blood glucose test results.

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)

**PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.**

**FOR FDA USE ONLY**

Concurrence of Center for Devices and Radiological Health (CDRH) (Signature)

**Katherine Serrano -S**

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This section applies only to requirements of the Paperwork Reduction Act of 1995.

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**Indications for Use**

510(k) Number (if known)  
K133647

Device Name  
EMV3.1 Self Monitoring Blood Glucose system

Indications for Use (Describe)

The EMV3.1 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 includes the speaking function but is not intended to be operated by visually impaired users. 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 EMV3.1 meter and the EMV3.1 test strips. The EMV3.1 meter only is used with the EMV3.1 test strips to quantitatively measure glucose in fresh capillary whole blood from fingertip, palm, or forearm.

The EMV3.1 Glucose Control Solution

For use with EMV3.1 Blood Glucose Self Monitoring System as a quality control check to verify the accuracy of blood glucose test results.

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)

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