



Food and Drug Administration  
10903 New Hampshire Avenue  
Silver Spring, MD 20993

EPS Bio Technology Corp.  
c/o Y.C. Lei  
General Manager  
No.8 R&D Rd III, Hsinchu Science Park  
Hsinchu City, Hsinchu  
China (Taiwan) 300

**SEP 07 2011**

Re: k112272  
Trade Name: EM44 Pro and EM44 Self Monitoring Blood Glucose System  
Regulation Number: 21 CFR §862.1345  
Regulation Name: Glucose test system  
Regulatory Class: Class II  
Product Codes: LFR, NBW, JJX  
Dated: August 2, 2011  
Received: August 8, 2011

Dear Mr. Lei:

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.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

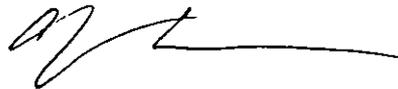
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's 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); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820).

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If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of *In Vitro* Diagnostic Device Evaluation and Safety at (301) 796-5450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (301) 796-5760. 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) 796-5680 or at its Internet address <http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,



Courtney H. Lias, Ph.D.  
Director  
Division of Chemistry and Toxicology  
Office of *In Vitro* Diagnostic Device  
Evaluation and Safety  
Center for Devices and Radiological Health

Enclosure

## Indications for Use

510(k) Number (if known): k112272

Device Name: **EM44 Self Monitoring Blood Glucose System**

Indications For Use:

The **EM44 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 **EM44 meter** and the **EM44 test strips**. The EM44 meter only is used with the EM44 test strips to quantitatively measure glucose in fresh capillary whole blood from fingertip, palm, or forearm.

### The **EM44 Glucose Control Solution**

For use with EM44 Self Monitoring Blood Glucose System as a quality control check to verify the accuracy of blood glucose test results.

Prescription Use \_\_\_\_\_  
(21 CFR Part 801 Subpart D)

And/Or

Over the Counter Use  X   
(21 CFR Part 801 Subpart C)

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Concurrence of CDRH, Office of In Vitro Diagnostic Device Evaluation and Safety (OIVD)



Division Sign-Off  
Office of In Vitro Diagnostic Device  
Evaluation and Safety

510(k)  K 112272

## Indications for Use

510(k) Number (if known): k112272

Device Name: **EM44 Pro Self Monitoring Blood Glucose System**

Indications For Use:

The **EM44 Pro Self Monitoring 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. Alternative site testing can be only used during steady-state blood glucose conditions.

The system consists of the **EM44 Pro meter** and the **EM44 Pro test strips**. The EM44 Pro meter only is used with the EM44 Pro test strips to quantitatively measure glucose in venous whole blood or fresh capillary whole blood from fingertip.

### The **EM44 Glucose Control Solution**

For use with EM44 Pro Self Monitoring Blood Glucose System as a quality control check to verify the accuracy of blood glucose test results.

Prescription Use   X    
(21 CFR Part 801 Subpart D)

And/Or

Over the Counter Use   X    
(21 CFR Part 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE; CONTINUE ON ANOTHER PAGE IF NEEDED)

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