



DEPARTMENT OF HEALTH & HUMAN SERVICES

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Food and Drug Administration  
10903 New Hampshire Avenue  
Document Mail Center – WO66-0609  
Silver Spring, MD 20993-0002

EPS Bio Technology Corporation  
c/o Mr. Y.C. Lei  
General Manager  
2F, No. 49-2, Lane 2, Sec. 2, Guang Fu Road  
Hsinchu City, China (Taiwan) 30071

**FEB 24 2010**

Re: k092894  
Trade/Device Name: EasyMax V SMBG System  
Regulation Number: 21 CFR §862.1345  
Regulation Name: Glucose Test System  
Regulatory Class: Class II  
Product Code: NBW, CGA  
Dated: January 21, 2010  
Received: January 25, 2010

Dear Mr. Y.C. 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).

Page 2

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,

A handwritten signature in black ink, appearing to read 'CCH', with a long horizontal flourish extending to the right.

Courtney C. Harper, 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): K092894

Device Name: **EasyMax V SMBG system**

### Indications for Use:

#### **EasyMax V SMBG Test System**

The EasyMax V Self Monitoring Blood Glucose Test System is intended for the quantitative measurement of glucose in fresh capillary whole blood samples drawn from the fingertips or forearm. Testing is done outside the body (In Vitro diagnostic use). It is indicated for use at home (over the counter [OTC]) by persons with diabetes, or in clinical settings by healthcare professionals, as an aid to monitor the effectiveness of diabetes control. In addition, this device is not intended for the diagnosis of or screening for diabetes and not intended to be used in visually impaired users and neonates.

#### **EasyMax V Meter**

The EasyMax V Meter is intended for the quantitative measurement of glucose in fresh capillary whole blood samples drawn from the fingertips or forearm. Testing is done outside the body (In Vitro diagnostic use). It is indicated for use at home (over the counter [OTC]) by persons with diabetes, or in clinical settings by healthcare professionals, as an aid to monitor the effectiveness of diabetes control. In addition, this device is not intended for the diagnosis of or screening for diabetes and not intended to be used in visually impaired users and neonates.

#### **EasyMax V Blood Glucose Test Strips**

The EasyMax V Blood Glucose Test Strips is intended for the quantitative measurement of glucose in fresh capillary whole blood samples drawn from the fingertips or forearm. Testing is done outside the body (In Vitro diagnostic use). It is indicated for use at home (over the counter [OTC]) by persons with diabetes, or in clinical settings by healthcare professionals, as an aid to monitor the effectiveness of diabetes control. In addition, this device is not intended for the diagnosis of or screening for diabetes and not intended to be used in visually impaired users and neonates.

#### **EasyMax V Glucose Control Solutions**

For use with the EasyMax V meter and EasyMax V Blood Glucose Test Strips as a quality control check to verify the accuracy of blood glucose test results.


Prescription Use   
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use   
(21 CFR 801 Subpart C)

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

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

  
Division Sign-Off

Office of In Vitro Diagnostic Device  
Evaluation and Safety

510(k) K092894