



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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

Food & Drug Administration
10903 New Hampshire Avenue
Building 66
Silver Spring, MD 20993

JUN 21 2010

JUL 1 2010

Re: k101457
Trade Name: EasyPlus mini R9N Self Monitoring Blood Glucose System
Regulation Number: 21 CFR §862.1345
Regulation Name: Glucose test system
Regulatory Class: Class II
Product Codes: CGA, NBW, JJX
Dated: May 21, 2010
Received: June 3, 2010

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 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):

K101457

10/1/03 2:31P

Device Name: EasyPlus mini R9N SMBG system

Indications for Use:

EasyPlus mini R9N SMBG Test System

The EasyPlus mini R9N SMBG 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. This device is not intended for the diagnosis or screening of diabetes mellitus and is not intended for use in neonates. Alternate Site Testing (AST) in the EasyPlus mini R9N Blood Glucose Monitoring System can be used only during steady-state blood glucose conditions.

EasyPlus mini R9N Meter

The EasyPlus mini R9N Meter is intended for the quantitative measurement of glucose in fresh capillary whole blood samples drawn from the fingertips or forearm. EasyPlus mini R9N Blood Glucose Test Strips must be used with the EasyPlus mini R9N Meter. 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. This device is not intended for the diagnosis or screening of diabetes mellitus and is not intended for use in neonates. Alternate Site Testing (AST) in the EasyPlus mini R9N Blood Glucose Monitoring System can be used only during steady-state blood glucose conditions.

EasyPlus mini R9N Blood Glucose Test Strips

The EasyPlus mini R9N Blood Glucose Test Strips, are intended for the quantitative measurement of glucose in fresh capillary whole blood samples drawn from the fingertips or forearm. EasyPlus mini R9N Blood Glucose Test Strips must be used with the EasyPlus mini R9N Blood Glucose Meter. Testing is done outside the body (*In Vitro* diagnostic use). They are 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. This device is not intended for the diagnosis or screening of diabetes mellitus and is not intended for use in neonates. Alternate Site Testing (AST) in the EasyPlus mini R9N Blood Glucose Monitoring System can be used only during steady-state blood glucose conditions.

EasyPlus mini R9N Glucose Control Solutions

For use with the EasyPlus mini R9N meter and EasyPlus mini R9N Blood Glucose Test Strips as a quality control check to verify the accuracy of blood glucose test results.

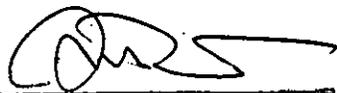
Prescription Use
(Part 21 CFR 801 Subpart D)

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)

K101457