K070053

DEC 0 3 2007

510(k) Summary

Submitter:	EPS Bio Technology Corp.
Contact Person:	Mr. Y.C. Lei, General Manager EPS Bio Technology Corp. 2F,No. 49-2, Lane 2, Guang Fu Rd.,Sec.2 Hsinchu City, Taiwan, R.O.C. Phone: 886-3-5752522 Fax: 886-3-5752552 E-mail: yclei@epsbio.com.tw
Date Prepared:	November 29, 2007
Trade Name:	EasyPlus mini Self Monitoring Blood Glucose Test System
Classification:	Glucose test system, 21 CFR 862.1345; Class II
Product Codes:	CGA, NBW, JJX
Predicate Device:	ACCU-CHEK advantage System (k032552)
Device Description:	The EasyPlus mini Self Monitoring Blood Glucose System is comprised of the EasyPlus mini Meter, EasyPlus mini Blood Glucose Test Strips, Auto Lancet, Check strip, Code card and Normal/High Control solutions.
Intended Use:	The EasyPlus mini 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.
Functional and Safety Testing:	A full array of in-house and clinical testing was done consistent with relevant FDA guidances for blood glucose monitoring systems. Bench testing included evaluation of interferences, sensitivity, linearity, reportable range, altitude effects, stability, precision and reproducibility. Clinical testing included evaluation of accuracy for both finger stick and Alternate Site Testing.
Conclusion:	Labeling, bench testing results and clinical testing results support the Indications for Use and the claim of substantial equivalence to the predicate.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

DEC 0 3 2007

EPS Biotechnology Corp.
c/o Mr. Y. C. Lei
General Manager
2F, No. 49-2, Lane 2
Guang Fu Road, Sec 2
Hsinchu City, Taiwan

Re: k070053
Trade/Device Name: EasyPlus Mini Self-Monitoring Blood Glucose System
Regulation Number: 21 CFR 862.1345
Regulation Name: Glucose test system.
Regulatory Class: Class II
Product Code: NBW, CGA, JJX
Dated: November 07, 2007
Received: November 13, 2007

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); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820).

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific information about the application of labeling requirements to your device, or questions on the promotion and advertising of your device, please contact the Office of In Vitro Diagnostic Device Evaluation and Safety at (240) 276-0490. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). 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 (240) 276-3150 or at its Internet address at http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Jean M. Cooper, M.S., D.V.M.

Jean M. Cooper, M.S., D.V.M.
Director
Division of Chemistry and Toxicology
Office of *In Vitro* Diagnostic Device
Evaluation and Safety
Center for Devices and
Radiological Health

Enclosure

Indication for Use

510(k) Number (if known): k070053
Device Name: EasyPlus min Self Monitoring Blood Glucose System
Indication For Use:
The EasyPlus mini Self Monitoring Blood Glucose Monitoring System is intended for in vitro diagnostic use (outside of body). It is indicated to be used by professional healthcare personnel or diabetics at home to measure glucose concentration for aiding diabetes management. The glucose concentration is measured with quantitative capillary whole blood from the fingertip, and forearm by using Easy Plus mini Monitoring Blood Glucose Monitoring System. The device is not intended for testing neonate blood samples.

EasyPlus mini Meter
The EasyPlus mini Meter is intended for the quantitative measurement of glucose in fresh capillary whole blood samples drawn from the fingertips or forearm. EasyPlus mini Blood Glucose Test Strips must be used with the EasyPlus mini 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.

The EasyPlus mini Test Strips
The EasyPlus mini 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 Blood Glucose Test Strips must be used with the EasyPlus mini 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.

The EasyPlus Normal/High Control Solution
For use with the EasyPlus mini meter and EasyPlus mini Blood Glucose Test Strips as a quality control check to verify the accuracy of blood glucose test results.

Prescription Use ___✓___ And/Or Over the Counter Use ✓
(21 CFR Part 801 Subpart D) (21 CFR Part 801 Subpart C)

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

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

Carol C. Benson
Division Sign-Off
Office of In Vitro Diagnostic Device
Evaluation and Safety

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