K120448

APR - 6 2012

510(k) Summary

Submitter:	Apex Biotechnology Corp. No. 7, Li-Hsin Road V, Hsinchu Science Park Hsinchu, 30078 CHINA (TAIWAN)
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Date Prepared:	February 6, 2012
Trade Names:	MEG-2B Blood Glucose Monitoring System MEG-2B Pro Blood Glucose Monitoring System MEG-2B Blood Glucose Test Strips MEG-2B Pro Blood Glucose Test Strips MEG-2B Glucose Control Solutions
Classification:	Glucose test system, 21 CFR 862.1345, Class II Single (specified) analyte controls (assayed and unassayed), Class I, 21 CFR 862.1660,
Product Codes:	CGA, NBW; JJX
Predicate Device:	MEG-2 Blood Glucose Monitoring System (k101204) MEG-2 Multi Blood Glucose Monitoring System (k101204) MEG-2 Blood Glucose Test Strip (k101204) MEG-2 Multi Blood Glucose Test Strip (k101204) MEG-2 Glucose Control Solution (k101204)
Device Description:	The MEG-2B blood glucose meter and MEG-2B test strips are used for testing of blood glucose by self-testers at home. The MEG-2B Pro meter and strips are identical to the MEG-2B versions except they are sold with labeling oriented toward the professional user, rather than the self-testing home user. MEG-2B Glucose Control Solutions are used for quality control testing of the system.

510(k) Summary (Continued)

Intended Use:	MEG-2B Blood Glucose Monitoring System: The MEG-2B Blood Glucose Monitoring System is intended for the quantitative measurement of glucose in fresh capillary whole blood samples drawn from the fingertips, forearm, or palm. It is indicated for lay use by people with diabetes as an aid to monitoring levels in Diabetes Mellitus and should only be used by a single patient. This system should not be shared. It is not indicated for the diagnosis or screening of diabetes or for neonatal use. MEG-2B Pro Blood Glucose Monitoring System: The MEG-2B Pro Blood Glucose Monitoring System is intended for the quantitative measurement of glucose in fresh capillary whole blood samples drawn from the fingertips, forearm, or palm. It is indicated to be use for multiple patients in a clinical setting by healthcare professionals, as an aid to monitoring levels in Diabetes Mellitus. This system is only used with single-use, auto-disabling lancing device. It is not indicated for the diagnosis or screening of diabetes or for neonatal use. MEG-2B Blood Glucose Test Strips: The MEG-2B Blood Glucose Test Strips are to be used with the MEG-2B Blood Glucose Meters to quantitatively measure glucose in capillary whole blood taken from fingertips, palm, or forearm. They are intended for lay use by people with diabetes and should only be used by a single patient. This system should not be shared. They are not indicated for the diagnosis or screening of diabetes or for neonatal use. MEG-2B Pro Blood Glucose Test Strips: The MEG-2B Pro Blood Glucose Test Strips are to be used with the MEG-2B Pro Blood Glucose Meter; it measures glucose in capillary whole blood taken from a fingertip, palm, or forearm. It is indicated in a clinical setting to be used for multiple patients by healthcare professionals. This system is only used with single-use, auto-disabling lancing device. MEG-2B Glucose Control Solutions: The purpose of the control solution test is to validate the performance of the Blood Glucose Monitoring System using a testing solution with a known range of glucose. A control test that falls within the acceptable range indicates the user's technique is appropriate and the test strip and meter are functioning properly.
Comparison of Technological Characteristics:	The MEG-2B system has been modified relative to the predicate by using a new test strip holder in the meter and a corresponding modified test strip. The MEG-2B meter uses the same test algorithm as the predicate meter. The MEG-2B control solutions use the same component chemicals as the predicate, with slightly modified glucose levels across the three control solutions. The MEG-2B Pro meter and strips are identical to the MEG-2B versions, except they are sold with labeling oriented toward the professional user, rather than the self-testing home user.
Non-Clinical Testing:	Testing was conducted as follows: EMC and Electrical Safety, drop testing, test strip holder qualification, software verification and validation (including unit integration testing), control solution qualification, and linearity testing with validation of Lo/Hi detection. Results demonstrate substantial equivalence to the predicate system.
Clinical Testing	Not applicable.
Conclusion:	Non-clinical testing demonstrated that the MEG-2B and MEG-2B Pro systems perform in a substantially equivalent manner to that of the predicate. We conclude that the two new systems are substantially equivalent to the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration

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Silver Spring, MD 20993

Apex Biotechnology Corp.
c.o Lisa Liu
No. 7, Li-Hsin Road V, Hsinchu Science Park
Hsinchu, 30078, Taiwan

APR - 6 2012

Re: k120448
Trade Name: MEG-2B Blood Glucose Monitoring System; MEG-2B Pro Blood Glucose Monitoring System; MEG-2B Glucose Control Solutions
Regulation Number: 21 CFR §862.1345
Regulation Name: Glucose Test System
Regulatory Class: Class II
Product Codes: NBW, CGA, JJX
Dated: March 16, 2012
Received: March 20, 2012

Dear Ms. Liu:

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).

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 Devices
Office of *In Vitro* Diagnostic Device
Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

Indications for Use Statement

510(k) Number (if known): K120448

Device Name: MEG-2B Blood Glucose Monitoring System

Indications for Use:

The MEG-2B Blood Glucose Monitoring System is intended for the quantitative measurement of glucose in fresh capillary whole blood samples drawn from the fingertips, forearm, or palm. It is indicated for lay use by people with diabetes as an aid to monitoring levels in Diabetes Mellitus and should only be used by a single patient. This system should not be shared. It is not indicated for the diagnosis or screening of diabetes or for neonatal use.

The MEG-2B Blood Glucose Test Strips are to be used with the MEG-2B Blood Glucose Meters to quantitatively measure glucose in capillary whole blood taken from fingertips, palm, or forearm. They are intended for lay use by people with diabetes and should only be used by a single patient. This system should not be shared. They are not indicated for the diagnosis or screening of diabetes or for neonatal use.

Prescription Use _____ (Part 21 CFR 801 Subpart D)	AND/OR	Over-The-Counter Use ___X___ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF 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) K120448

Indications for Use Statement

510(k) Number (if known): K120448

Device Name: MEG-2B Pro Blood Glucose Monitoring System

Indications for Use:

The MEG-2B Pro Blood Glucose Monitoring System is intended for the quantitative measurement of glucose in fresh capillary whole blood samples drawn from the fingertips, forearm, or palm. It is indicated to be use for multiple patients in a clinical setting by healthcare professionals, as an aid to monitoring levels in Diabetes Mellitus. This system is only used with single-use, auto-disabling lancing device. It is not indicated for the diagnosis or screening of diabetes or for neonatal use.

The MEG-2B Pro Blood Glucose Test Strips are to be used with the MEG-2B Pro Blood Glucose Meter; it measures glucose in capillary whole blood taken from a fingertip, palm, or forearm. It is indicated in a clinical setting to be used for multiple patients by healthcare professionals. This system is only used with single-use, auto-disabling lancing device.

Prescription Use ___X___ (Part 21 CFR 801 Subpart D)	AND/OR	Over-The-Counter Use ___X___ (21 CFR 801 Subpart C)

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

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Evaluation and Safety
510(k) 120448

Indications for Use Statement

510(k) Number (if known): K 120448

Device Name: MEG-2B Glucose Control Solutions

Indications for Use:

The purpose of the control solution test is to validate the performance of the Blood Glucose Monitoring System using a testing solution with a known range of glucose. A control test that falls within the acceptable range indicates the user's technique is appropriate and the test strip and meter are functioning properly.

Prescription Use _____ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use ___X___ (21 CFR 801 Subpart C)

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