K113098

JAN 17 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:	January 10, 2012
Trade Names:	AutoSure Voice II Plus Blood Glucose Monitoring System AutoSure Plus Blood Glucose Test Strips Contrex Plus III Glucose Control Solutions
Classification:	Glucose test system, 21 CFR 862.1345, Class II Single (specified) analyte controls (assayed and unassayed), 21 CFR 862.1660, Class I
Product Codes:	CGA, NBW, JJX
Predicate Device:	AutoSure Voice II Blood Glucose Monitoring System (k102037)
Device Description:	The AutoSure Voice II Plus blood glucose meter and AutoSure Plus blood glucose test strips are used for testing of blood glucose by self-testers at home with Contrex Plus III Glucose Control Solutions for quality control testing.

510(k) Summary (Continued)

Intended Use:	AutoSure Voice II Plus Blood Glucose Monitoring System: The AutoSure Voice II Plus 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. The meter includes voice functionality to assist visually impaired users. 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 and it should not be shared. It is not indicated for the diagnosis or screening of diabetes or for neonatal use. AutoSure Plus Blood Glucose Test Strips: The AutoSure Plus Blood Glucose Test Strips are to be used with the AutoSure Voice II Plus Blood Glucose Meter to quantitatively measure glucose in capillary whole blood taken from fingertips, palm, or forearm. They are not indicated for the diagnosis or screening of diabetes or for neonatal use. Contrex Plus III 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 AutoSure Voice II Plus meter is identical to the predicate AutoSure Voice II meter. The AutoSure Plus test strip is nearly identical to the predicate AutoSure test strip, differing only due to minor changes in chemistry and the size of the sample chamber and is exactly identical to the GAL-1C test strip (k102816). The Contrex Plus III control solutions include a red dye not in the Contrex Plus predicate and the concentrations of the ingredients are slightly different. The Contrex Plus III control solutions in this submission are identical to the solutions cleared under k102816, and have now been qualified for usage with the new AutoSure Voice II Plus system.
Non-Clinical Testing:	Testing was conducted as follows: Precision, analytical specificity (interferences), linearity, Lo/Hi detection, minimum sample volume, altitude, hematocrit, humidity and temperature, control solution qualification, and environmental conditions testing. Results demonstrate substantial equivalence to the predicate device meter, test strips, and control solutions.
Clinical Testing	An accuracy study was performed with blood testing by healthcare professionals. A User Performance study was conducted with self-testing at finger, palm, and forearm sites. Results demonstrate substantial equivalence to the predicate system.
Conclusion:	Clinical and non-clinical testing demonstrated that the AutoSure Voice II Plus system performs in a substantially equivalent manner to that of the predicate system. We conclude that the AutoSure Voice II Plus meter, AutoSure Plus test strips and Contrex Plus III control solutions are substantially equivalent to the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration

10903 New Hampshire Avenue
Silver Spring, MD 20993

Apex BioTechnology Corporation
c/o Hsue-mei Lee
Manager of Quality Assurance Department
No. 7 Li-Hsin Road V, Hsinchu Science Park
Hsinchu, China (Taiwan) 30078

JAN 17 2012

Re: k113098
Trade Name: AutoSure Voice II Plus Blood Glucose Monitoring System
Regulation Number: 21 CFR §862.1345
Regulation Name: Glucose Test System
Regulatory Class: Class II
Product Codes: NBW, CGA, JJX
Dated: December 13, 2011
Received: December 15, 2011

Dear Hsue-mei Lee:

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): k113098

Device Name: AutoSure Voice II Plus Blood Glucose Monitoring System

Indications for Use:

AutoSure Voice II Plus Blood Glucose Monitoring System:

> The AutoSure Voice II Plus 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. The meter includes voice functionality to assist visually impaired users. 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 and it should not be shared. It is not indicated for the diagnosis or screening of diabetes or for neonatal use.

AutoSure Plus Blood Glucose Test Strips:

> The AutoSure Plus Blood Glucose Test Strips are to be used with the AutoSure Voice II Plus Blood Glucose Meter to quantitatively measure glucose in capillary whole blood taken from fingertips, palm, or forearm. 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) K113098

Indications for Use Statement

510(k) Number (if known): k113098

Device Name: Contrex Plus III 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)

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

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

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