APR 2 8 2011

510(k) Summary

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Date Prepared:	April 18, 2011
Trade Names:	AutoSure Voice 3 Blood Glucose Monitoring System, AutoSure Blood Glucose Test Strips
Classification:	Glucose test system, 21 CFR 862.1345, Class II
Product Codes:	CGA, NBW
Predicate Devices:	AutoSure Voice II meter and AutoSure test strips
Device Description:	The AutoSure Voice 3 blood glucose monitoring system consists of the AutoSure Voice 3 meter and AutoSure Test Strips. It is used for testing of blood glucose by self-testers at home.

Intended Use:	System: The AutoSure Voice 3 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. Testing is done outside the body (In Vitro diagnostic use). 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. It is not indicated for the diagnosis or screening of diabetes or for neonatal use. Test Strip: The AutoSure Blood Glucose Test Strips are to be used with the AutoSure Voice II and AutoSure Voice 3 Blood Glucose Meters to quantitatively measure glucose in capillary whole blood taken from fingertips, palm, or forearm. The AutoSure Voice II and AutoSure Voice 3 Blood Glucose Monitoring Systems are plasma-calibrated for easy comparison to lab results. They are intended for self-testing by persons with diabetes and should be used by a single patient. They are not indicated for the diagnosis or screening of diabetes or for neonatal use.
Comparison of Technological Characteristics:	The AutoSure Voice 3 meter uses the same test algorithm, test strip, and control solutions as the predicate. Meter dimensions and button locations were modified relative to the predicate.
Non-Clinical Testing:	Testing was conducted as follows: Software verification and validation, software integration, linearity, strip holder reliability, test strip noninterchangeability, and EMC & Electrical Safety. Results demonstrate substantial equivalence to the predicate device.
Clinical Testing	An accuracy study was performed with blood testing by healthcare professionals. Results demonstrate substantial equivalence to the predicate device.
Conclusion:	Clinical and non-clinical testing demonstrated that the AutoSure Voice 3 meter with the AutoSure Test Strip perform in a substantially equivalent manner to that of the predicate device. We conclude that the AutoSure Voice 3 system is substantially equivalent to the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993

APR 28 2011

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

Re: k102481
Trade Name: AutoSure Voice 3 Blood Glucose Monitoring System
Regulation Number: 21 CFR 862.1345
Regulation Name: Glucose Test System
Regulatory Class: Class II
Product Code: CGA, NBW, JJX
Dated: April 18, 2011
Received: April 20, 2011

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 Parts 801 and 809), 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 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) 796-7100 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Courtney 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 Statement

510(k) Number (if known): k102481

Device Name: AutoSure Voice 3 Blood Glucose Monitoring System

Indications for Use:

AutoSure Voice 3 Blood Glucose Monitoring System:

The AutoSure Voice 3 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. Testing is done outside the body (In Vitro diagnostic use). 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. It is not indicated for the diagnosis or screening of diabetes or for neonatal use.

AutoSure Blood Glucose Test Strips:

The AutoSure Blood Glucose Test Strips are to be used with the AutoSure Voice II and AutoSure Voice 3 Blood Glucose Meters to quantitatively measure glucose in capillary whole blood taken from fingertips, palm, or forearm. The AutoSure Voice II and AutoSure Voice 3 Blood Glucose Monitoring Systems are plasma-calibrated for easy comparison to lab results. They are intended for self-testing by persons with diabetes and should only be used by a single patient. They are not indicated for the diagnosis or screening of diabetes or for neonatal use.

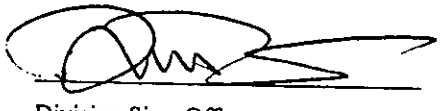
Prescription Use _____ (Part 21 CFR 801 Subpart D)

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) k102481