K090413

APR 09 2009

5 510(k) Summary

Submitter:	Thomas Y.S. Shen, Chairman & CEO Apex BioTechnology Corp. No. 7, Li-Hsin Road V, Hsinchu Science Park Hsinchu, 30078, CHINA (TAIWAN)
Contact Person:	Thomas Y.S. Shen, Chairman & CEO Apex BioTechnology Corp. No. 7, Li-Hsin Road V, Hsinchu Science Park Hsinchu, 30078, CHINA (TAIWAN) email: tyshen@apexbio.com Phone: 011-886-3-5641952 FAX: 011-886-3-5678302
Date Prepared:	December 31, 2008
Trade Name:	AutoSure Voice Blood Glucose Monitoring System
Classification:	Glucose test system, 21 CFR 862.1345, Class II
Product Codes:	CGA, NBW, JJX
Predicate Device:	GlucoSure Voice BGM System
Device Description:	AutoSure Voice consists of a meter, test strips, and control solutions for use in measuring blood glucose as an aid to monitor the effectiveness of diabetes control
Intended Use:	The AutoSure Voice 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 both lay use by people with diabetes and in a clinical setting by healthcare professionals, as an aid to monitoring levels in Diabetes Mellitus.
Functional and Safety Testing:	Linearity testing confirmed that the use of a preset meter calibration code did not have an adverse effect on accuracy or precision. The ability to detect results below and above the reportable range and to display Lo and Hi, respectively, was verified. Software verification and validation demonstrated that modifications did not lead to software defects in system function.
Conclusion:	The modification to the original device does not adversely affect performance and the modified device is substantially equivalent to the unmodified predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

APR 09 2009

Apex BioTechnology Corporation
c/o Thomas Y.S. Shen
No.7, Li-Hsin Road V
Hsinchu Science Park
Hsinshu, China (Taiwan) 30078

Re: k090043
Trade Name: AutoSure Voice 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: March 10, 2009
Received: March 13, 2009

Dear Mr. Shen:

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 (301) 594-3084. 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 (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html.

Sincerely yours,

Courtney C. Harper, Ph.D.
Acting Director
Division of Chemistry and Toxicology
Office of *In Vitro* Diagnostic Device
Evaluation and Safety
Center for Devices and Radiological Health

4. Indications for Use Statement

510(k) Number (if known): k090043

Device Name: AutoSure Voice Blood Glucose Monitoring System

Indications For Use:

AutoSure Voice Blood Glucose Monitoring System:

The AutoSure Voice 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 both lay use by people with diabetes and in a clinical setting by healthcare professionals, as an aid to monitoring levels in Diabetes Mellitus. It is not indicated for the diagnosis or screening of diabetes or for neonatal use.

AutoSure Voice Test Strips:

The AutoSure Voice Blood Glucose Test Strips are to be used with the AutoSure Voice Blood Glucose Meter to quantitatively measure glucose in capillary whole blood taken from fingertips, palm, or forearm. The AutoSure Voice System is plasma-calibrated for easy comparison to lab result. The AutoSure Voice Blood Glucose Monitoring System is intended for self-testing by persons with diabetes and by health care professionals. It is 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)

Carol C Benson

Division Sign-Off

Office of In Vitro Diagnostic Device Evaluation and Safety

K090043