K102037

AUG 13 2010

6 510(k) Summary

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Date Prepared:	July 2, 2010
Trade Names:	AutoSure Voice II 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 meter and test strips
Device Description:	The AutoSure Voice II blood glucose monitoring system consists of a meter and AutoSure test strips. It is used for testing of blood glucose by self-testers at home and for professional testers in healthcare facilities.

510(k) Summary (Continued)

Intended Use:	System: The AutoSure Voice II 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. Test Strip: The AutoSure Blood Glucose Test Strips are to be used with the AutoSure Voice II Blood Glucose Meter to quantitatively measure glucose in capillary whole blood taken from fingertips, palm, or forearm. The AutoSure Voice II Blood Glucose Monitoring System is plasma-calibrated for easy comparison to lab results. It 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.
Comparison of Technological Characteristics:	The AutoSure Voice II meter uses the same test algorithm as the predicate. The meter has been modified by relocating the 3 operating buttons. Meter software has been changed to accommodate the new autocoding feature. The test strip and test strip holder have been modified to allow automatic detection of the calibration code upon insertion of the test strip. The test strip is otherwise unchanged from the predicate test strip.
Non-Clinical Testing:	Testing was conducted as follows: Software verification and validation, software integration, linearity, Lo/Hi detection, strip holder reliability, drop testing, EMC and Electrical Safety, autocode manufacturing qualification, and verification of strip noninterchangeability between new and predicate devices. Results demonstrate substantial equivalence to the predicate device.
Clinical Testing	An accuracy study was performed with blood testing by healthcare professionals. A user study was conducted to evaluate ease-of-use of the system and ease-of-understanding of the User's Manual. Results demonstrate substantial equivalence to the predicate device.
Conclusion:	Clinical and non-clinical testing demonstrated that the AutoSure Voice II meter and AutoSure test strips perform in a substantially equivalent manner to that of the predicate device. We conclude that the AutoSure Voice II meter and AutoSure test strips are substantially equivalent to the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food & Drug Administration
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AUG 13 2010

Re: k102037
Trade Name: AutoSure Voice II Blood Glucose Monitoring System
Regulation Number: 21 CFR §862.1345
Regulation Name: Glucose test system
Regulatory Class: Class II
Product Codes: CGA, NBW
Dated: July 2, 2010
Received: July 19, 2010

Dear Mr. 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 C. 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

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5 Indications for Use Statement

510(k) Number (if known): K102037

Device Name: AutoSure Voice II Blood Glucose Monitoring System

Indications for Use:

AutoSure Voice II Blood Glucose Monitoring System:

The AutoSure Voice II 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 Blood Glucose Test Strips:

The AutoSure Blood Glucose Test Strips are to be used with the AutoSure Voice II Blood Glucose Meter to quantitatively measure glucose in capillary whole blood taken from fingertips, palm, or forearm. The AutoSure Voice II Blood Glucose Monitoring System is plasma-calibrated for easy comparison to lab results. It 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)

Division Sign-Off
Office of In Vitro Diagnostic Device
Evaluation and Safety

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