

K073648

APR 10 2008

5 510(k) Summary

Submitter:	Thomas Y.S. Shen Apex BioTechnology Corp. No. 7, Li-Hsin Road V, Hsinchu Science Park Hsinchu, 30078 CHINA (TAIWAN) Phone: 011-886-3-5641952 FAX: 011-886-3-5678302
Contact Person:	Thomas Y.S. Shen
Date Prepared:	December 21, 2007
Trade Name:	GlucoSure Star Blood Glucose Monitoring System
Classification:	Glucose test system, 21 CFR 862.1345, Class II
Product Codes:	CGA, NBW, JJX
Predicate Device:	GlucoTrack Blood Glucose Monitoring System (k062799)
Device Description:	GlucoSure Star 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:	<p>"The GlucoSure Star Blood Glucose Monitoring System is intended for the quantitative measurement of glucose in fresh capillary whole blood taken from fingertips, palm, or forearm. Testing is done outside the body (<i>In Vitro</i> diagnostic use). 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."</p> <p>The GlucoSure Star is identical to the GlucoTrack except for the addition of the palm and forearm sampling site claims.</p>
Functional and Safety Testing:	Clinical testing was done with persons with diabetes to verify proper performance for Alternate Site Testing (AST) using palm and forearm blood sampling. Professional fingertip meter results were compared with AST results collected both by professionals and by persons with diabetes. Data were analyzed by linear regression analysis, Clarke Error Grid analysis and bias analysis. Results met pass/fail performance criteria.
Conclusion:	The addition of the AST blood sampling claim does not adversely affect performance of the device. The new device with the modified AST blood sampling claim is substantially equivalent to the predicate device with its original Intended Use.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

Apex Biotechnology Corp.
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Chairman & CEO
No. 7, Li-Hsin Road V
Hsinchu Science Park
Hsinchu, 30078 Taiwan, ROC

APR 10 2008

Re: k073648
Trade Name: Glucosure Star Blood Glucose Monitoring System, Model as90000e1
Regulation Number: 21 CFR 862.1345
Regulation Name: Glucose Monitoring System
Regulatory Class: Class II
Product Codes: NBW, CGA
Dated: February 21, 2008
Received: February 25, 2008

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).

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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 (240) 276-0490. 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 (240) 276-3150 or at its Internet address at <http://www.fda.gov/cdrh/industry/support/index.html>.

Sincerely yours,

Jean M. Cooper, M.S., D.V.M.

Jean M. Cooper, M.S., D.V.M.

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): K073648

Device Name: GlucoSure Star Blood Glucose Monitoring System

Indications For Use:

GlucoSure Star Blood Glucose Monitoring System:

The GlucoSure Star Blood Glucose Monitoring System is intended for the quantitative measurement of glucose in fresh capillary whole blood taken from fingertips, palm, or forearm. Testing is done outside the body (In Vitro diagnostic use). The GlucoSure Star System is plasma-calibrated for easy comparison to lab results. 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.

GlucoSure Star Test Strips:

The GlucoSure Star Blood Glucose Test Strips are to be used with the GlucoSure Star Blood Glucose Meter to quantitatively measure glucose in capillary whole blood taken from fingertips, palm, or forearm.

Prescription Use _____ AND/OR Over-The-Counter Use X
(Part 21 CFR 801 Subpart D) (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) K073648
