K982076

DEC 10 1998

Amira Medical ATLAST Blood Glucose Monitoring System
510(k) Premarket Notification

510(k) SUMMARY

Submitter's Name, Address, Telephone Number, and Contact Person

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Contact Person: Nina Peled, Ph.D.
Vice President, Scientific Affairs

Date Prepared: June 10, 1998

Name of Device and Name/Address of Sponsor

Trade name: ATLAST Blood Glucose Monitoring System

Amira Medical
4742 Scotts Valley Road
Scotts Valley, CA 95065

Classification Names:

Colorimeter, photometer, spectrophotometer for clinical use (21 C.F.R. § 862.2300);
Glucose oxidase, glucose test system (21 C.F.R. § 862.1345)
Single analyte control (21 C.F.R. § 862.1660)
Blood lancet (21 C.F.R. § 878.4800)

Predicate Devices

1. LifeScan One Touch Basic Blood Glucose Monitoring System (K922888)
2. Boehringer Mannheim Accu-Chek Easy Blood Glucose Monitoring System (K923048)

Intended Use/Indications

The ATLAST Blood Glucose Monitoring System is intended to be used for the quantitative measurement of glucose in whole blood. It is intended for use by people with diabetes mellitus in the home as an aid to monitor the effectiveness of diabetes control. It is not intended for use in the diagnosis of or screening for diabetes mellitus and is not intended for use on neonates. The ATLAST Blood Glucose Monitoring System is specifically indicated for the quantitative measurement of glucose in whole blood samples obtained from the finger, forearm, upper arm and the thigh.

Device Description

The ATLAST Blood Glucose Monitoring System measures the amount of glucose in capillary whole blood. When whole blood is applied to the ATLAST Test Strip, reagents on the Test Strip react with the blood and a color is formed, the intensity of which is measured by the ATLAST System. The ATLAST Blood Glucose Monitoring System consists of the following components: (1) a reflectance photometer which incorporates a lancing device ("ATLAST System"), (2) glucose reagent test strips ("ATLAST Test Strips") and calibration chip, and (3) sterile lancets ("ATLAST Lancets").

Principle of Operation

The user obtains a blood sample using the ATLAST System. A sterile lancet is inserted into the lancing component of the ATLAST System by inserting a sterile lancet into the sampler head and re-attaching it to the ATLAST System. The unit is cocked by pulling the cocking knob until it latches, then the user releases the knob. With the sampler head positioned firmly on the forearm, the user fully depresses the body of the unit which releases the lancet to pierce the skin. Immediately following the lancing action, the lancet is automatically retracted. A sliding motion is required to obtain an adequate blood sample. While maintaining the lancet and sampler head in position on the sample site, the body of the unit is depressed and released several times to draw blood from the incision point. After obtaining a sample, the user is ready to touch the test strip to the blood sample to begin the testing process.

The user inserts the test strip into the test strip holder of the ATLAST System and turns the ATLAST System on. The test strip is then brought to the lancing site and the user touches the capillary tip of the ATLAST Test Strip to the blood sample. Blood is drawn into the test strip by capillary action. The meter "beeps" when an adequate blood sample has been received and the testing sequence begins.

The glucose in the blood sample reacts with glucose oxidase to yield gluconic acid. This reaction is catalyzed by the peroxidase present in the test strip. The hydrogen peroxide formed then oxidizes the dye couple in the test strip. This reaction, which is catalyzed by the enzyme peroxidase, oxidizes the dye couple to form a dye that intensifies in color with increasing glucose concentrations. The color change on the reagent test strip pad is proportional to the concentration of the glucose present in the whole blood sample.

The user obtains blood glucose results in approximately 10-30 seconds, depending on glucose levels. The ATLAST System will "beep" when the test is complete and the blood glucose results will appear on the meter display.

Data Demonstrating Substantial Equivalence

Performance testing on the ATLAST Blood Glucose Monitoring System demonstrated that the System meets or exceeds the performance requirements for the intended clinical use of the device. Laboratory/Bench Testing was conducted in accordance with FDA's draft guidance, *Review Criteria for Assessment of Portable Blood Glucose Monitoring In-Vitro Diagnostic Devices Using Glucose Oxidase Methodology*. The results demonstrated that the ATLAST Blood Glucose Monitoring System satisfies all of its performance specifications, which are designed to ensure that the System is safe and effective for its intended use.

A multi-center, subject controlled clinical study was conducted to evaluate the accuracy of the ATLAST Blood Glucose Monitoring System when used by lay users with diabetes mellitus and by experienced technicians trained in blood glucose testing techniques. In addition, the ATLAST Blood Glucose Monitoring System was compared to a predicate blood glucose monitoring system. Blood glucose results obtained with the ATLAST Blood Glucose Monitoring System and predicate device were compared to results obtained using a laboratory reference method for measuring blood glucose levels.

The clinical data demonstrate that the performance of the ATLAST Blood Glucose Monitoring System correlates well with the laboratory blood glucose reference test method. When the blood glucose test results were analyzed by the Error Grid Analysis of Clarke et al., the System provided results within the range of clinically acceptable accuracy. The data also demonstrate that the ATLAST Blood Glucose Monitoring System's performance is substantially equivalent to that of a predicate device. The clinical data demonstrate that the ATLAST Blood Glucose Monitoring System performs equivalently in the hands of the diabetic lay user and when used by a trained technician.

Conclusion

Laboratory/Bench Testing and Clinical Correlation Studies demonstrate that the Amira Medical ATLAST Blood Glucose Monitoring System is safe and effective for its intended use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

DEC 10 1998

Nina Peled, Ph.D.
Vice President, Scientific Affairs
Amira Medical
4742 Scotts Valley Road
Scotts Valley, California 95065

Re: K982076
Trade Name: ATLAST Blood Glucose Monitoring System
Regulatory Class: II
Product Code: CGA
Dated: June 10, 1998
Received: June 12, 1998

Dear Dr. Peled:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we 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). 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 (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 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 advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4588. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification"(21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers 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,

Steven Gutman

Steven I. Gutman, M.D., M.B.A.
Director
Division of Clinical
Laboratory Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K982076

Device Name: Amira Medical ATLAST Blood Glucose Monitoring System

Indications For Use:

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The ATLAST Blood Glucose Monitoring System is specifically indicated for the quantitative measurement of glucose in whole blood samples obtained from the finger, forearm, upper arm and the thigh.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Clinical Laboratory Devices
510(k) Number K982076

Prescription Use_____ OR Over-The-Counter Use ✓
(Per 21 CFR 801.109)

(Optional Format 1-2-96)