K011233

MAY 1 8 2001

510 (k) SUMMARY

1. SUBMITTED BY:

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Hypoguard USA, Inc.
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952-646-3188 (phone)
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Summary prepared April 20, 2001

2. NAME OF DEVICE:

Trade Name:	GlucoSure Blood Glucose Monitoring System
Common Names/Descriptions:	Blood glucose meter system
Classification Names:	Glucose test system, product code 75CGA, 21 CFR 862.1345

3. PREDICATE DEVICE: GlucoSure Blood Glucose Monitoring System

4. DEVICE DESCRIPTION:

Blood glucose monitoring system. The GlucoSure Blood Glucose Monitoring System consists of a meter, test strips, and control solution. It is intended for over-the-counter, home use by diabetics to monitor their blood glucose levels and for professional use. The system tests capillary whole blood. The meter is a portable, battery-operated instrument.

5. INTENDED USE:

This modification does not alter the original intended use:

The GlucoSure Blood Glucose Monitoring System is intended for the quantitative measurement of glucose in fresh capillary whole blood. Testing is done outside the body (*in vitro* diagnostic use). It is indicated for use at home (over the counter [OTC]) by persons with diabetes, or in clinical settings by health care professionals, as an aid to monitor the effectiveness of diabetes control.

6. SUMMARY OF TECHNOLOGICAL CHARACTERISTICS

The modification has not altered the GlucoSure system technological characteristics.

The GlucoSure Meter is a battery operated meter that measures the electronic current generated from the reaction of glucose with the chemical reagents impregnated into a disposable electrode. Glucose in the blood sample reacts with glucose oxidase in the test strip, liberating electrons that produce a micro-current. The intensity of the current, as measured by the meter, correlates with the concentration of glucose in the sample. The measured current is electronically converted and displayed digitally on the meter's LCD.

7. NON-CLINICAL TESTING

Hematocrit Study: The hematocrit effect was evaluated at 5 hematocrit levels and 5 glucose levels spanning the claimed ranges. Testing was done using hematocrit-adjusted venous blood spiked with dextrose. YSI plasma data was used for comparison. Results showed that the modification to plasma-referenced format did not alter performance characteristics other than to shift results consistent with plasma-referencing.

8. CLINICAL TESTING

Not Applicable.

9. CONCLUSIONS FROM TESTING

Testing demonstrated that the modification did not alter performance characteristics other than by converting the system from whole blood-referenced to plasma-referenced.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

MAY 1 8 2001

Bruce A, MacFarlane, Ph.D.
Vice President
Regulatory Affairs and Quality Systems
Hypoguard USA, Inc.
5182 West 76th Street
Minneapolis,. MN 55439

Re: 510(k) Number: K011233
Trade/Device Name: GlucoSure Blood Glucose Monitoring System
Touch-In Blood Glucose Test Strips
Contrex Glucose Control Solutions
Regulation Number: 862.1345
Regulatory Class: II
Product Code: CGA
Dated: April 20, 2001
Received: April 23, 2001

Dear Dr. MacFarlane:

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 to 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 Good Manufacturing Practice for Medical Devices: General (GMP) regulation (21 CFR Part 820) and that, through periodic GMP 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" (21CFR 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

INDICATIONS FOR USE

510(k) Number (if known):

Device Name: GlucoSure Blood Glucose Monitoring System
Touch-In Blood Glucose Test Strips
Contrex Glucose Control Solutions

Indications For Use:
The GlucoSure Blood Glucose Monitoring System is intended for the quantitative measurement of glucose in fresh capillary whole blood. Testing is done outside the body (*in vitro* diagnostic use). It is indicated for use at home (over the counter [OTC]) by persons with diabetes, or in clinical settings by health care professionals, as an aid to monitor the effectiveness of diabetes control.

Touch-In Blood Glucose Test Strips are intended for use with the GlucoSure and GlucoSmart blood glucose meters for the quantitative measurement of glucose in fresh capillary whole blood. Testing is done outside the body (in vitro diagnostic use). The test strips are indicated for use at home (over the counter [OTC]) by persons with diabetes, or in clinical settings by health care professionals, as an aid to monitor the effectiveness of diabetes control.

Contrex Control Solutions are aqueous glucose solutions for use with the Sensorex, GlucoSure, GlucoSure II and GlucoSmart Blood Glucose Monitoring Systems and Touch-In Test Strips. They are used as a quality control check to verify the accuracy of your blood glucose test result.

Contrex Glucose Control solutions are intended for use in the validation of the performance of the Blood Glucose Monitoring System by providing a test solution with a known range of glucose. A control test that falls within the acceptable range indicates the user's technique is appropriate and the test strip and meter are functioning properly.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-O
Division of Clin. ...boratory Devices
510(k) Number K011733

(Optional Format 3-10-98)