K024347

MAR 2 8 2003

510(k) Summary

1. SUBMITTED BY:	Bruce A. MacFarlane, Ph.D. 5182 West 76th Street Edina, MN 55439 USA Summary prepared: 20th December 2002
2. NAME OF DEVICES:	
Trade Names:	Express Blood Glucose Monitoring System Express Strip Reader Express Test Strips Express High Control Solution Express Normal Control Solution
Common Names/Descriptions:	Blood glucose monitoring system
Classification Names:	- Glucose test system, product codes CGA, NBW, 21 CFR 862.1345 - Single (specified) analyte controls (assayed/unassayed), product code JJX, 21 CFR 862.1660
Regulatory Status:	Class II
PREDICATE DEVICE:	Hypoguard Advance™ Blood Glucose Monitoring System

3. DEVICE DESCRIPTION:

The Express Blood Glucose Monitoring System includes a disposable meter containing 100 biosensors (test strips) plus control solution. It is intended for over-the-counter, home use by diabetics to monitor their blood glucose levels, or for use in a clinical setting by healthcare professionals. The system tests fresh capillary whole blood. The meter is a portable, battery-operated instrument.

4. INTENDED USE:

The Express 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 a clinical setting by health care professionals, as an aid to monitor the effectiveness of diabetes control.

5. SUMMARY OF TECHNOLOGICAL CHARACTERISTICS

The Express Blood Glucose Monitoring System has the same technological characteristics as the predicate device, except that it has self-contained test strips.

6. NON-CLINICAL TESTING

Precision Study: Testing was performed using venous whole blood spiked to provide samples at six glucose concentrations across the performance range of the system. The within-run precision tests consisted of twenty replicates inclusive of the six-spiked whole blood glucose reference levels recommended by FDA Guidance Document. The within-run tests were performed within four hours of blood collection. The between-run precision tests consisted of twenty replicates per day at the six glucose concentrations using six tests with six different blood dlonors. The within-run and between-run precision values were substantially equivalent to that of the predicate.

Hematocrit Study: The hematocrit effect was evaluated at a range of hematocrit levels from 30% to 55%. YSI plasma-referenced data was used for comparison. Results showed acceptable accuracy within this hematocrit range.

Altitude Study: Testing was conducted using two control solutions and capillary whole blood spiked to three different levels. The study was performed at ≈800-feet and ≈10,000-feet elevations. Evaluation of mean values and CVs indicated no significant effect of high elevation on performance. The Express Blood Glucose Monitoring System is qualified at altitudes up to 10,000 ft. above sea level.

Dynamic Range/Linearity: Testing was conducted using venous blood spiked with D-glucose to provide samples to test the 20-600 mg/dL dynamic range. Testing was conducted using Express Strip Readers, and one YSI glucose analyzer. The results demonstrated good performance across the 20-600 mg/dL range.

7. CLINICAL TESTING

Accuracy/method correlation testing was done comparing the Express Strip Reader against the predicate and the YSI 2300 analyzer (reference method). Testing included both men and women, both Type 1 and Type 2 diabetes, ages from eighteen to eighties, and a wide range of educational levels. Tested blood glucose values encompassed the 30-90 mg/dL range on the low end to values over 250 mg/dL at the high end. Linear regressions statistics showed good correlation between Express Strip Reader results and the YSI plasma reference method, whether testing was carried out by the clinician or the patient. Regression statistics were substantially equivalent to those obtained for the predicate device.

8. CONCLUSIONS FROM TESTING

Testing demonstrated that the performance of the Express Blood Glucose Monitoring System was substantially equivalent to that of the predicate.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

MAR 2 8 2003

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

Re: k024347
Trade/Device Name: Express Blood Glucose Monitoring System
Regulation Number: 21 CFR 862. 1345
Regulation Name: Glucose Test Systems
Regulatory Class: Class II
Product Code: CGA , NBW
Dated: December 20, 2002
Received: December 30, 2002

Dear Dr. MacFarlane:

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,

Steven Gutman

Steven I. Gutman, M.D., M.B.A.
Director
Office of *In Vitro* Diagnostic Device
Evaluation and Safety
Center for Devices and
Radiological Health

Enclosure

Indications For Use

510(k) Number (if known):

Device Name: Express Blood Glucose Monitoring System

Indications For Use:

Express Blood Glucose Monitoring System:

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Express Control Solution:
Express Control Solution is intended for use with the Express as a quality control check to verify the accuracy of blood glucose test results. Use the Express Control Solution to verify that the Express System is functioning properly.

Jean Cooper

(Division Sign-Off)
Division of Clinical Laboratory Devices
510(k) Number K024347

Rx ✓ OTC ✓

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Optional Format 3-10-98)