K031388

MAY 22 2003

510 (k) SUMMARY

1. SUBMITTED BY:

Bruce A. MacFarlane, Ph.D.
Hypoguard USA, Inc.
5182 West 76th Street
Minneapolis, MN 55439
952-646-3188 (phone)
952-646-3110 (fax)

Summary prepared: 29 April, 2003

2. NAME OF DEVICE:

Trade Name:	Hypoguard Advance 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: Hypoguard Advance Blood Glucose Monitoring System

4. DEVICE DESCRIPTION:

The Hypoguard Advance 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, or for use in a clinical setting by health care professionals. The system tests fresh capillary whole blood. The meter is a portable, battery-operated instrument designed for use with Hypoguard Advance Blood Glucose Test Strips.

5. INTENDED USE:

This modification does not alter the original intended use:

The Hypoguard Advance 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 healthcare professionals, as an aid to monitor the effectiveness of diabetes control.

6. SUMMARY OF TECHNOLOGICAL CHARACTERISTICS

The modification has not altered the Hypoguard Advance Blood Glucose Monitoring System technological characteristics.

The modified Hypoguard Advance System has the same technological characteristics as the original device.

7. NON-CLINICAL TESTING

Precision Study: Testing was performed identically to the original Advance 510(k). Within run, between run and total CV% were calculated identically to original 510(k). Acceptance criteria were met. Dynamic range claims and minimum sample volume claims were validated.

8. CLINICAL TESTING

Accuracy/method correlation testing was done comparing the modified Hypoguard Advance System against the original Hypoguard Advance System and the YSI 2300 analyzer (reference method). Testing included both men and women, both Type I and Type II diabetes, ages from nineteen to the eighties, and a wide range of educational levels. Tested blood glucose values encompassed the 25-80 mg/dL range on the low end to values over 250 mg/dL at the high level. Acceptance criteria were met, including Clarke Error Grid Analysis.

9. CONCLUSIONS FROM TESTING

Testing demonstrated that the results were within acceptance criteria. Therefore the modification did not adversely affect performance characteristics.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

MAY 22 2003

Bruce A. MacFarlane, Ph.D.
Quality Assurance Manager
Hypoguard USA, Inc.
5182 West 76th Street
Minneapolis, MN 55439

Re: k031388
Trade/Device Name: Hypoguard Advance Blood Glucose Monitoring System
Regulation Number: 21 CFR 862.1345
Regulation Name: Glucose Test System
Regulatory Class: Class II
Product Code: NBW, CGA
Dated: April 29, 2003
Received: May 2, 2003

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). Other general information on your responsibilities under the Act may be obtained 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: Hypoguard Advance Blood Glucose Monitoring System

Indications For Use:

Hypoguard Advance Blood Glucose Monitoring System:
The Hypoguard Advance 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 healthcare professionals, as an aid to monitor the effectiveness of diabetes control.

Hypoguard Advance Blood Glucose Meter:
The Hypoguard Advance Blood Glucose Meter 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 healthcare professionals, as an aid to monitor the effectiveness of diabetes control.

Hypoguard Advance Blood Glucose Test Strips:
The Hypoguard Advance Blood Glucose Meter 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 healthcare professionals, as an aid to monitor the effectiveness of diabetes control.

Hypoguard Advance Control Solution:
Hypoguard Advance Control Solution is intended for use with the Hypoguard Advance Meter and Hypoguard Advance Test Strips as a quality control check to verify the accuracy of blood glucose test results.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

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

Jean Cooper
Division Sign-Off

Office of In Vitro Diagnostic Device Evaluation and Safety

510(k) K031388

(Optional Format 3-10-98)