DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

OCT 29 2002

Hypoguard USA, Inc.
c/o Mr. Mark Job
Responsible Third Party Official
510(k) Program Manager
TUV Product Service
1775 Old Highway 8 NW, Suite 104
New Brighton, MN 55112-1891

Re: k020232
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: January 11, 2002
Received: January 14, 2002

Dear Mr. Job:

This SE Letter corrects SE Letter stamp dated February 12, 2002. The previous letter was not sent to the Third Party, Mr. Mark Job, but to Dr. Bruce MacFarlane. This letter also corrects the Received Date from January 14, 2001 to January 14, 2002. This letter now corrects both errors.

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 the Code of Federal Regulations, Title 21, Parts 800 to 898. 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 Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

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 advice for your device on our labeling regulation (21 CFR Part 801 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-__. 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 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
Division of Clinical Laboratory Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

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 use with Hypoguard ADVANCE™ Blood Glucose Test Strips 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 Test Strips are intended for use with Hypoguard ADVANCE™ Blood Glucose Meter 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)

(Division Sign-Off)
Division of Clinical Laboratory Devices
510(k) Number K020232

(Optional Format 3-10-98)