K022545

OCT 11 2002

SECTION 2. SUMMARY AND CERTIFICATION

A. 510(k) Summary

Submitter: Hypoguard USA, Inc.

Contact Person:
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Date Prepared: July 31, 2002

Trade Name: GlucoBalance Data Management Software

Classification Name and Number: Glucose Test System, Class II, 21 CFR 862.1345

Calculator/Data Processing Module, Class I, 21 CFR 862.2100

Product Codes: CGA, NBW and JQP

Predicate Device(s): Camit Data Management System from Roche Diagnostics Corp. (K001907).

Device Description The GlucoBalance Data Management Software is an optional accessory for use with Hypoguard blood glucose meters with data management capabilities. The subject device consists of a data transfer cable and software. The system allows the user to download blood glucose results from their glucose meter to their computer, maintain a history of their glucose test results, and convert them into graphs, charts and reports. It should be noted that the software does not recommend any medical treatment or medication dosage level.

Intended Use: Intended Use: GlucoBalance™ Data Management Software is an optional accessory for use with Hypoguard blood glucose meters with data management capabilities. GlucoBalance transfers data from the meter's memory into a computer for enhanced data management. GlucoBalance is intended for use in home and clinical settings to assist people with diabetes and their health care

professionals in review, analysis and evaluation of historical blood glucose test results to support diabetes management.

Functional and Safety Testing:

Representative samples of the subject device underwent performance testing to demonstrate appropriate functional characteristics. The testing included validation of the systems hardware (the data transfer cable) and software as well as consumer studies that demonstrated the systems ability to be easily operated by in-home users.

Conclusion:

The GlucoBalance Data Management Software is substantially equivalent to the Camit Data Management System from Roche Diagnostics Corp. (K001907).

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

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OCT 11 2002

Re: k022545
Trade/Device Name: GlucoBalance Data Management Software
Regulation Number: 21 CFR 862.1345
Regulation Name: Glucose test system
Regulatory Class: Class II
Product Code: NBW, JQP
Dated: July 31, 2002
Received: August 1, 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 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 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 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

Enclosure

Indications For Use Page

510(k) Number (if known): K022545

Device Name: GlucoBalance Data Management Software

Indications for Use:

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

prescription ✓ over the counter

(Division Sign-Off)
Division of Clinical Laboratory Devices
510(k) Number K022545

(Optional Format 3-10-98)