

JUN 16 1997

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15971276

**510(k) SAFETY AND EFFECTIVENESS SUMMARY**

**Prepared:** April 3, 1997

**Submitter:** Bayer Corporation, Business Group Diagnostics

**Address:** 1884 Miles Avenue, P. O. Box 70  
Elkhart, IN 46515  
(219) 262-6929

**Contact:** Rosanne M. Savol, R.A.C.  
Manager, Regulatory Affairs

**Device:** Trade/Proprietary Name: GLUCOMETER ENCORE® QA+ Blood  
Glucose Meter (Neonatal Modification)  
Common/Usual Name: Test for glucose in blood  
Document Control Number: K97 \_\_\_\_\_

**Classification:** Division of Clinical Laboratory Devices  
Panel - Clinical Chemistry and Toxicology  
Classification Code - 75 CFR (Hexokinase, Glucose)

**Predicate Devices:** GLUCOMETER ENCORE® Blood Glucose Monitoring System  
ACCU-CHEK® ADVANTAGE® Blood Glucose System (Boehringer  
Mannheim Corporation)  
YSI Blood Glucose Analyzer (Yellow Springs Instrument  
Company, Inc.)

**Device Description:** The GLUCOMETER ENCORE QA+ Blood Glucose Meter is part of  
the GLUCOMETER ENCORE Blood Glucose Monitoring System. The  
GLUCOMETER ENCORE Blood Glucose Monitoring System is an  
over-the-counter home testing system for measuring glucose in blood.  
The System is for use by persons with diabetes and by healthcare  
professionals in home settings and in healthcare facilities.

**Intended Use:** GLUCOMETER ENCORE QA+ Blood Glucose Meter is for the Self-Monitoring of Blood Glucose as an adjunct to the care of persons with diabetes\* The GLUCOMETER ENCORE QA+ Blood Glucose Meter (Neonatal Modification) can be used to measure glucose in capillary and venous blood specimens, arterial specimens and neonatal specimens.

**Technological Characteristics:** The GLUCOMETER ENCORE QA+ Blood Glucose Meter is a reflectance photometer used with GLUCOMETER ENCORE® Blood Glucose Test Strips to determine the glucose concentration in whole blood. The modified instrument minimizes the optical and chemical interferences of hemoglobin with the test strips. Accurate results can be obtained at hematocrit levels and glucose levels that are seen in neonatal populations.

**Assessment of Performance:** The performance of the GLUCOMETER ENCORE QA+ Blood Glucose Meter (Neonatal Modification) was evaluated in studies in-house and in healthcare facilities with neonatal blood specimens. The results of the studies demonstrated good performance in comparison to clinical laboratory blood glucose analyzers.

**Conclusion:** The results of the clinical evaluation of the GLUCOMETER ENCORE QA+ Blood Glucose Meter (Neonatal Modification) on neonatal blood specimens demonstrated that the device is equivalent in performance to the predicate devices and suitable for use with neonatal blood specimens.

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\* "Consensus Statement on Self-Monitoring of Blood Glucose," Diabetes Care, Vol. 10, No. 1, January-February 1987, pp. 95-99.



Food and Drug Administration  
2098 Gaither Road  
Rockville MD 20850

JUN 16 1997

Rosanne M. Savol, R.A.C.  
• Manager, Regulatory Affairs  
Bayer Corporation  
1884 Miles Avenue  
P.O. Box 70  
Elkhart, Indiana 46514-0070

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Re: K971276  
GLUCOMETER ENCORE® QA+Blood Glucose Meter (Modified)  
Regulatory Class: II  
Product Code: CFR  
Dated: April 3, 1997  
Received: April 7, 1997

Dear Ms. Savol:

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 (for the indications for use stated in the enclosure) 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 (Pre-market 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 pre-market 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.

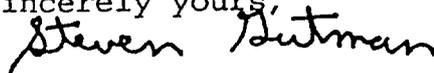
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Under the Clinical Laboratory Improvement Amendments of 1988 (CLIA-88), this device may require a CLIA complexity categorization. To determine if it does, you should contact the Centers for Disease Control and Prevention (CDC) at (770) 488-7655.

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" (21 CFR 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/dsmamain.html>".

Sincerely yours,



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

510(k) Number (if known): \_\_\_\_\_

Device Name: GLUCOMETER ENCORE® QA+ Blood Glucose Monitoring System

Indications for Use: The GLUCOMETER ENCORE QA+ Blood Glucose Monitoring System is an over-the-counter (OTC) home test for glucose in blood. The system is for use by persons with diabetes and by healthcare professionals in home settings and in healthcare facilities. The frequent monitoring of blood glucose is an adjunct to the care of persons with diabetes. The GLUCOMETER ENCORE QA+ Blood Glucose Monitoring System can be used with capillary and venous blood specimens, arterial blood specimens and neonatal blood specimens.

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

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Concurrence of CDRH, Office of Device Evaluation (ODE)

  
\_\_\_\_\_  
(Division Sign-Off)  
Division of Clinical Laboratory Devices

510(k) Number

K 9712176

Prescription Use   
(Per 21 CFR 801.109)

OR

Over-The-Counter Use

(Optional Format 1-2-96)