

JUN 30 1999

K991242

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### 510(k) SAFETY AND EFFECTIVENESS SUMMARY

Prepared: April 9, 1999

Submitter: Bayer Corporation, Business Group Diagnostics

Address: 1884 Miles Avenue, P.O. Box 70  
Elkhart, IN 46515  
(219) 262-6928

Contact: George M. Tancos R.A.C.  
Manager, Regulatory Compliance

Device: Trade/Proprietary Name: GLUCOMETER ELITE® Test Strips  
Common/Usual Name: Test for glucose in blood  
Document Control Number: K991242

Classification Name: The GLUCOMETER ELITE® Test Strips and the GLUCOMETER ELITE® family of blood glucose meters are used to test for glucose in blood. In 21 CFR 862.1345, a glucose test system is classified as a Class II medical device.

Predicate Device: GLUCOMETER ELITE® Test Strips  
Manufactured by: The GLUCOMETER ELITE® Test Strips are produced by Arkray KDK Corporation of Kyoto, Japan.

Device Description: The GLUCOMETER ELITE® Test Strips (Modified) are for use with the GLUCOMETER ELITE® family of blood glucose meters. The GLUCOMETER ELITE® Blood Glucose Test System is an over-the-counter (OTC) home test for glucose in blood. The system is used by persons with diabetes and by healthcare professionals in home settings and in healthcare facilities.

Intended Use: The GLUCOMETER ELITE® Blood Glucose Test Systems are used for self-monitoring of blood glucose as an adjunct to the care of persons with diabetes.

**Technological Characteristics:**

The GLUCOMETER ELITE® Blood Glucose Test Systems are specific for glucose and have been referenced to give plasma/serum equivalent glucose results. These test systems provide a quantitative measurement of glucose in whole blood from 20 - 600 mg/dL (1.1 to 33.3 mmol/L).

The GLUCOMETER ELITE® Test Strips are based on the measurement of electrical potential caused by the reaction of glucose with the reagents (Glucose Oxidase method) on the electrode of the strip.

**Assessment of Performance:**

An in-house evaluation of the performance of the GLUCOMETER ELITE® Test Strips (Modified) was conducted to demonstrate and verify the performance with a 2 µL blood sample. The studies indicate that the GLUCOMETER ELITE® Test Strips with the reduced volume are suitable for their intended use.

**Conclusion:**

The results of the evaluation of the GLUCOMETER ELITE® Test Strips (Modified) demonstrate satisfactory performance with 2 µL of specimen and are suitable for their intended use.



DEPARTMENT OF HEALTH & HUMAN SERVICES

JUN 30 1999

Food and Drug Administration  
2098 Gaither Road  
Rockville MD 20850

Mr. George M. Tancos, R.A.C.  
Manager, Regulatory Compliance  
Bayer Corporation  
Business Group Diagnostics  
1884 Miles Avenue  
P.O. Box 70  
Elkhart, Indiana 46515-0070

Re: K991242  
Trade Name: GLUCOMETER ELITE® Test Strips (Modified)  
Regulatory Class: II  
Product Code: CGA  
Dated: April 9, 1999  
Received: April 12, 1999

Dear Mr. Tancos:

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 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). 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 (Premarket 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 Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS 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 premarket notification submission does not affect any obligation you might

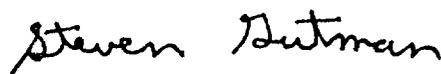
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Under the Clinical Laboratory Improvement Amendments of 1988 (CLIA-88), this device may require a CLIA complexity categorization. To determine if it does, you should contact the Centers for Disease Control and Prevention (CDC) at (770) 488-7655.

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/dsma/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): K99 1242

Device Name: **GLUCOMETER ELITE® Test Strips**

**Indications for Use:** The GLUCOMETER ELITE® Test Strips are used with the GLUCOMETER ELITE® XL Blood Glucose Meter and the GLUCOMETER ELITE® Blood Glucose Test Systems to measure the glucose level in whole blood. The GLUCOMETER ELITE® XL and GLUCOMETER ELITE® Blood Glucose Systems are home-use (OTC) devices used by persons with diabetes, and by healthcare professionals in clinical settings for the self-monitoring of blood glucose and as an adjunct to the care of persons with diabetes.

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

\_\_\_\_\_  
Concurrence of CDRH, Office of Device Evaluation (ODE)

*Carol Benson & Jean Cooper*  
\_\_\_\_\_  
(Division Sign-Off)  
Division of Clinical Laboratory Devices  
510(k) Number K991242

Prescription Use \_\_\_\_\_  
(Per 21 CFR 801.109)

OR

Over-The-Counter Use   
(Optional Format 1-2-96)