3/18/99

K984006

510(k) SAFETY AND EFFECTIVENESS SUMMARY

Prepared:	November 6, 1998
Submitter:	Bayer Corporation, Business Group Diagnostics
Address:	1884 Miles Avenue, P.O. Box 70 Elkhart, IN 46515 (219) 262-6928
Contact:	George M. Tancos, RAC Manager, Regulatory Compliance
Device:	Trade/Proprietary Name: GLUCOMETER Elite® XL Blood Glucose Meter Common/Usual Name: Blood Glucose Meter Document Control Number: K98_____
Classification:	Division of Clinical Laboratory Devices Panel – Clinical Chemistry and Toxicology Classification Code – 75CGA (Glucose Oxidase, Glucose)
Predicate Devices:	GLUCOMETER Elite® Blood Glucose Meter Manufactured by KDK Corporation of Kyoto, Japan
Device Description:	The GLUCOMETER Elite XL System consists of an electrochemical method-based meter and dry reagent sensor (test strips) designed for testing glucose by persons with diabetes or by healthcare professionals in the home or in healthcare facilities.
Intended Use:	The GLUCOMETER Elite XL Blood Glucose Meter is for the Self-Monitoring of Blood Glucose as an adjunct to the care of person with diabetes.[1]

[1] "Consensus Statement on Self-Monitoring of Blood Glucose, " *Diabetes Care,* Vol. 10, No. 1, January-February 1987, pp. 95.99

Technological Characteristics:

The GLUCOMETER Elite XL Blood Glucose Meter has internal engineering design changes. The memory features have been expanded to include storing up to 120 test results, registering the time and date a test is performed. This data can then be used to provide a 14-day blood glucose average. In addition, the GLUCOMETER Elite XL Blood Glucose Meter has the capability to down load stored data to a computer system which can electronically summarize data in a logbook report, graph, or chart via the WinGlucofacts™ Diabetes Management Software. The algorithm was modified to provide greater accuracy at low glucose concentrations. Cosmetic changes to the case include a rounded top, a larger display window, and a button to access the setup menu and memory functions.

Assessment of Performance:

An evaluation of the GLUCOMETER Elite XL Blood Glucose Meter was conducted at two clinical sites to demonstrate the equivalence of the new meter to the currently used GLUCOMETER Elite Blood Glucose Meter, the predicate device, in the hands of diabetics and healthcare professionals.

Conclusion:

The results of the evaluation of the GLUCOMETER Elite XL Blood Glucose Meter demonstrate that the new meter is equivalent in performance to the predicate device and suitable for its intended use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

MAR 18 1999

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

Re: K984006
Trade Name: GLUCOMETER Elite® XL Blood Glucose Meter
Regulatory Class: II
Product Code: CGA
Dated: February 9, 1999
Received: February 10, 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 have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

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 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

510(k) Number (if known): K984006

Device Name: GLUCOMETER Elite® XL Blood Glucose Meter

Indications for Use: The GLUCOMETER Elite XL Blood Glucose Meter is used with GLUCOMETER Elite® Test Strips and Controls for the measurement of glucose in whole blood. The GLUCOMETER Elite System is an Over-the-Counter (OTC) device used 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.

Kim Cooper

(Division Sign-Off)
Division of Clinical Laboratory Devices
510(k) Number K984006

(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)