K043311

DEC 22 2004

510(k) Summary of Safety and Effectiveness

Submitter Information

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Date Prepared:	November 30, 2004

Device Information

Proprietary Name:	Ascensia ELITE™ Blood Glucose Meter
Common Name:	Blood Glucose Meter
Classification:	Division of clinical laboratory Devices Panel --- Clinical Chemistry and Toxicology classification Code 75 CGA (Glucose Oxidase, Glucose)

Predicate Device Information

Name:	Ascensia ELITE™ Blood Glucose Meter
Manufacturer:	Bayer HealthCare LLC 430 S. Bieger Street Mishawaka, In 46544
510(k) Number(s):	K020208/K964630

Device Description

The Ascensia ELITE™ Diabetes Care 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.

Statement of Intended Use:

The Ascensia ELITE™ Diabetes Care System is for the Self-Monitoring of Blood Glucose as an adjunct to the care of person with diabetes.[1]

Summary of Technological Characteristics:

The Ascensia ELITE™ Diabetes Care System is based on an electrode sensor technology. Capillary action at the end of the Test Strip draws a small amount of blood into the reaction chamber and a reading is displayed in 30 seconds. The Test Strips are foiled and available in packages of 25, 50, or 100 counts. Blood glucose results are referenced to plasma glucose. The System has a linear response to glucose from 20-600 mg/dL.

Performance Data:

An evaluation of the Ascensia ELITE™ Diabetes Care System was studied to verify and validate that the microprocessor change did not adversely affect or change the performance characteristics of the system. These studies demonstrated that users can obtain blood glucose results that are substantially equivalent to current methods for blood glucose.

Conclusion:

The results of verification and validation evaluations of the Ascensia ELITE™ Diabetes Care System demonstrate that the device is equivalent in performance to the predicate device and suitable of its intended use.

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

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

DEC 22 2004

Mr. George M. Tancos
Manager, Regulatory Affairs
Bayer HealthCare LLC
Diabetes Care Division
1884 Miles Avenue, PO Box 70
Elkhart, IN 46514-0070

Re: k043311
Trade/Device Name: Ascensia ELITE™ Diabetes Care System
Regulation Number: 21 CFR 862.1345
Regulation Name: Glucose test system
Regulatory Class: Class II
Product Code: NBW, CGA
Dated: November 30, 2004
Received: December 1, 2004

Dear Mr. Tancos:

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 Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. 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 Parts 801 and 809); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820).

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 information about the application of labeling requirements to your device, or questions on the promotion and advertising of your device, please contact the Office of In Vitro Diagnostic Device Evaluation and Safety at (301) 594-3084. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act 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,

Cornelia B. Rooks

Cornelia B. Rooks, MA
Acting Director
Division of Chemistry and Toxicology
Office of In Vitro Diagnostic Device
Evaluation and Safety
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K043311

Device Name: **Ascensia ELITE™ Diabetes Care System**

Indications for Use: **The Ascensia ELITE™ Blood Glucose Meter is used with Ascensia ELITE™ Blood Glucose Test Strips, and Ascensia ELITE™ Controls for the measurement of glucose in whole blood from specimens taken from the fingers or an alternate puncture site within certain conditions. The Ascensia ELITE™ Diabetes Care 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.

Prescription Use _____ AND/OR Over-The-Counter Use -XX-
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

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

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

Carol C. Benson
Division Sign-Off

Office of In Vitro Diagnostic
Device Evaluation and Safety

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