MAR 0 3 2003

510(k) SAFETY AND EFFECTIVENESS SUMMARY

Prepared:	December 2, 2002	
Submitter:	Bayer Corporation, Business Group Diagnostics	
Address:	1884 Miles Avenue P.O. Box 70 Elkhart, IN 46515 574.262.6928	
Contact:	George M. Tancos RAC Manager, Regulatory Affairs	
Device:	Trade/Proprietary Name:	Ascensia ™ BREEZE™ Blood Glucose Meter
	Common/Usual Name:	Test for glucose in whole blood -- Blood Glucose Meter
	Document Control Number:	K024062
Classification Name:	Division of Clinical laboratory Devices Panel -- Clinical Chemistry and Toxicology Classification Code -- 75 CGA (Glucose Oxidase, Glucose) In 21 CFR 862.1345, a glucose test system is classified as a Class II medical device.	
Predicate Devices:	ASCENSIA™ DEX® 2 Manufactured by: Bayer Diagnostics, Mishawaka, IN	
Device Description:	The ASCENSIA™ BREEZE™ consists of an electrochemical method-based meter and dry reagent sensors (test strips) designed for testing glucose by persons with diabetes.	
Intended Use:	The ASCENSIA™ BREEZE™ Blood glucose Meter is for the Self-Monitoring of Blood Glucose as an adjunct to the care of persons with diabetes.[1]	

[1] "Consensus Statement on Self-Monitoring of Blood glucose," Diabetes *Care,* vol. 10, No. 1, January-February 1987, pages 95-99.

Technological Characteristics:	The electronics of the ASCENSIA™ BREEZE™ Blood Glucose Meter employs an amperometric glucose oxidase method to measure glucose in blood. It is conceptually similar as other blood glucose testing monitoring systems available for blood glucose testing. The Reagent Test Sensors are individually sealed in cartridges of ten sensors. Blood glucose results are reference to plasma glucose. The ASCENSIA™ BREEZE™ Blood Glucose Meter has a linear response to glucose from 10-600 mg/dL.
Assessment of Performance:	An evaluation of the ASCENSIA™ BREEZE™ Blood Glucose Meter was conducted at five clinical sites to demonstrate the equivalence of the ASCENSIA™ BREEZE™ Blood glucose meter to the Ascensia DEX 2 Blood Glucose Meter, the predicate device, in the hands of diabetics.
Conclusion:	The results of the evaluation of the ASCENSIA™ BREEZE™ Blood Glucose Meter demonstrate hat the meter is equivalent in performance to the predicate device and suitable for its intended use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

MAR 0 3 2003

Mr. George M. Tancos
Manager, Regulatory Affairs
Bayer HealthCare LLC
Diagnostics Division
1884 Miles Avenue
P.O. Box 70
Elkhart, IN 46515-0070

Re: k024062
Trade/Device Name: ASCENSIA™ BREEZE™ Blood Glucose Meter
Regulation Number: 21 CFR 862.1345
Regulation Name: Glucose test system
Regulatory Class: Class II
Product Code: NBW; CGA
Dated: February 18, 2003
Received: February 24, 2003

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,

Steven Gutman

Steven I. Gutman, M.D., M.B.A.
Director
Office of *In Vitro* Diagnostic Device
Evaluation and Safety
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K024062

Device Name: ASCENSIA™ BREEZE™ Blood Glucose Meter

Indications for Use:

The ASCENSIA BREEZE Blood Glucose Meter is used with the ASCENSIA™ AUTODISC™ Blood Glucose Test Strips and ASCENSIA™ AUTODISC™ CONTROLS for the measurement of glucose in whole blood. The ASCENSIA BREEZE Blood Glucose Meter is an Over-the-Counter (OTC) device used by persons with diabetes and by healthcare professionals in home settings.

The ASCENSIA BREEZE Blood Glucose System is indicated for use with venous, and capillary whole blood samples drawn from the fingertip, palm, forearm, abdomen and thigh.

The frequent monitoring of blood glucose is an adjunct to the care of persons with diabetes.

Dean Cooper

(Division Sign-Off)
Division of Clinical Laboratory Devices
510(k) Number K024062

(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) and

(Optional Format 1-2-96)