NOV 2 0 2002 K023584

510(k) Summary of Safety and Effectiveness

Submitter Information

Contact person:	George M. Tancos
Address:	1884 Miles Avenue Elkhart, IN 46515
Phone:	574.262.6928
FAX:	574.262.6945
E-mail:	george.tancos.b@bayer.com

Date Prepared:	October 11, 2002

Device Information

Proprietary Name:	ASCENSIA™ DEX® 2 Diabetes Care System
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™ DEX® 2 Blood Glucose Meter
Manufacturer:	Bayer Diagnostics 430 S. Beiger Street Mishawaka, In 46544
510(k) Number:	K020210

Device Description

The ASCENSIA™ DEX®2 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™ DEX®2 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™ DEX®2 Diabetes Care System employs an amperometric glucose oxidase method to measure glucose in blood. It is conceptually the same as other blood glucose monitoring products available for blood glucose testing. The test sensor discs are individually sealed in a package of ten. Blood glucose results are referenced to plasma glucose. The System has a linear response to glucose from 10-600 mg/dL.

Performance Data:

An evaluation of the ASCENSIA™ DEX® 2 Diabetes Care System was studied in-house and in clinical settings by healthcare professionals and by persons with diabetes. The studies demonstrated that users can obtain blood glucose results that are substantially equivalent to current methods for blood glucose.

Conclusion:

The results of in-house and clinical evaluations of the ASCENSIA™ DEX® 2 Diabetes Care System demonstrate that the device is equivalent in performance to the predicate devices 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

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

NOV 2 0 2002

Mr. George M. Tancos R.A.C.
Manager Regulatory Affairs
Bayer Corporation
1884 Miles Avenue
P.O. Box 70
Elkhart, IN 46515-0070

Re: k023584
Trade/Device Name: ASCENSIA™ DEX®2 Diabetes Care System
Regulation Number: 21 CFR 862.1345
Regulation Name: Glucose Test System
Regulatory Class: Class II
Product Code: NBW; CGA
Dated: October 22, 2002
Received: October 25, 2002

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). Other general information on your responsibilities under the Act may be obtained 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): K023584

Device Name: ASCENSIA™ DEX®2 Diabetes Care System

Indications for Use: The ASCENSIA™ DEX®2 Blood Glucose Meter is used with ASCENSIA™AUTODISC™ Blood Glucose Test Strips GLUCOMETER® DEX® Test Sensor and Controls for the measurement of glucose in whole blood. The ASCENSIA™ DEX®2 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.

(Division Sign-Off)
Division of Clinical Laboratory Devices
510(k) Number K023584

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Clinical Laboratory Devices
510(k) Number K023584

Prescription Use_____ OR Over-The-Counter Use ✓
(Per 21 CFR 801.109)