K024234

JAN 23 2003

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:	574.262.4945
E-mail:	george.tancos.b@bayer.com

Date Prepared:	December 19, 2002

Device Information

Proprietary Name:	The Ascensia™ ^{Win}Glucofacts® Ascensia™ WinGlucofacts® Professional
Common Name:	Software and connecting Cable
Classification:	Division of Clinical Laboratory Devices Panel – Clinical Chemistry and Toxicology Classification Code 21 CFR 862.2100 (75 JQP Calculator/Data Processing Module, for Clinical Use)

Predicate Device Information

Name:	Glucofacts® Data Management System
Manufacturer:	Bayer Diagnostics 430 S. Bieger Street Mishawaka, In 46544
510(k) Number:	K861844

Device Description

The Ascensia ^{Win}Glucofacts and the Ascensia ^{Win}Glucofacts Professional software consist of a CD, and a connecting cable. It is to be used with a *compatible* blood glucose meter and a Personal Computer (PC). The software provides data management of patient blood glucose results and uses standard statistical and graphical tools/techniques to facilitate the review of the data by individuals or health care professionals.

Statement of Intended Use:

The Ascensia ^{Win}Glucofacts and the Ascensia ^{Win}Glucofacts Professional software provides data management of patient blood glucose results and uses standard statistical and graphical tools/techniques to facilitate the review of data by individuals or health care professionals.

Summary of Technological Characteristics:

The Ascensia ^{Win}Glucofacts and the Ascensia ^{Win}Glucofacts Professional software is used to capture blood glucose meter results and graphically display the information. It uses standard statistical and graphical tools/techniques to facilitate the review of the data by individuals or health care professionals.

Performance Data:

Internal and external Performance/Validation studies were conducted. The studies demonstrate satisfactory performance of the Ascensia ^{Win}Glucofacts and the Ascensia ^{Win}Glucofacts Professional software in the hands of end users.

Conclusion:

The results of in-house and external evaluations of the Ascensia ^{Win}Glucofacts and the Ascensia ^{Win}Glucofacts Professional software demonstrate that these devices are equivalent in performance to the predicate devices and suitable of its intended use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

JAN 23 2003

Mr. George M. Tancos R.A. C.
Manager, Regulatory Affairs
Bayer Corporation
1884 Miles Avenue, P.O. Box 70
Elkhart, IN 46514-0070

Re: k024234
Trade/Device Name: Ascensia™ WINGlucofacts®
Ascensia™ WINGlucofacts® Professional
Regulation Number: 21 CFR 862.1345
Regulation Name: Glucose test system
Regulatory Class: Class II
Product Code: NBW, JQP
Dated: December 19, 2002
Received: December 23, 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): K_____

Device Name: Ascensia™ WinGlucofacts®
Ascensia™ WinGlucofacts® Professional

Indications for Use: The Ascensia WinGlucofacts and the Ascensia WinGlucofacts Professional software are accessories to the Ascensia™ Blood Glucose monitoring systems. The Ascensia WinGlucofacts and the Ascensia WinGlucofacts Professional software are Over-The Counter (OTC) devices used by persons with diabetes and by healthcare professionals for data transfer in the home and in healthcare facilities.

(Division Sign-Off)
Division of Clinical Laboratory Devices
510(k) Number K024234

(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)