K992085

MAY 2 5 2000

510(k) Summary

Abbott IMx ® Glycated Hemoglobin II

Submitter:
Abbott Laboratories
Abbott Diagnostics Division
200 Abbott Park Road
Abbott Park, IL 60064
(847) 938-7707

Contact Person:
Katherine M. Wortley

Date Prepared:
April 26, 2000

Product Trade and Common Name:
Abbott IMx ® Glycated Hemoglobin II

Classification Name:
Class II, 81LCP
21 CFR 864.7470 Glycosylated Hemoglobin Assay

Predicate Device:
Bio-Rad DIAMAT™ Glycosylated Hemoglobin Analyzer System (K851636)

Description and Intended Use of the Device:
The Abbott IMx Glycated Hemoglobin II assay is a boronate affinity binding assay using Ion Capture separation for the quantitative determination of percent glycated hemoglobin in human anticoagulated whole blood (EDTA, lithium heparin, or sodium heparin) on the Abbott IMx analyzer. Glycated hemoglobin measurements are used in the management of diabetes mellitus. The Abbott IMx Glycated Hemoglobin II assay is calibrated with Abbott IMx Glycated Hemoglobin II Calibrators. Abbott IMx Glycated Hemoglobin II Controls are assayed for the verification of the accuracy and precision of the Abbott IMx Analyzer.

Technical Characteristics Compared to Predicate:
The technical characteristics of the two systems are presented in the table below:

Assay Characteristics	Bio-Rad DIAMAT™ Glycosylated Hemoglobin Analyzer System	IMx® Glycated Hemoglobin II
Analyte Measured: Reported	Glycated Hemoglobin: %A1c	Glycated Hemoglobin: %A1c and %GHb
Assay Principle	Ion exchange liquid chromatography (HPLC)	Boronate affinity Ion Capture
Instrumentation	DIAMAT Analyzer System	IMx Analyzer
Standardization	Traceable to the Diabetes Control and Complications Trial (DCCT) reference method. Certified via the National Glycohemoglobin Standardization Program (NGSP).	Traceable to the Diabetes Control and Complications Trial (DCCT) reference method. Certified via the National Glycohemoglobin Standardization Program (NGSP).
Sample Type	Human anticoagulated whole blood (EDTA, potassium oxalate or sodium fluoride).	Human anticoagulated whole blood (EDTA, lithium heparin, and sodium heparin)

Testing to Establish Substantial Equivalence:
Substantial equivalence has been demonstrated between the IMx Glycated Hemoglobin II assay and the Bio-Rad DIAMAT Glycosylated Hemoglobin Analyzer System. The intended use for both the IMx Glycated Hemoglobin II assay and the Bio-Rad DIAMAT Glycosylated Hemoglobin Analyzer System is the quantitative determination of glycated hemoglobin in human anticoagulated whole blood. A correlation study was done to compare the two assays. The results are presented in the following table:

Regression Method	n	r	Slope	Intercept
Least Squares	247	0.976	0.94	0.45
Passing-Bablok	247	0.976	0.98	0.13

Conclusion:
In conclusion, these data demonstrate that the IMx Glycated Hemoglobin II is substantially equivalent to, the Bio-Rad DIAMAT Glycosylated Hemoglobin Analyzer System.

DEPARTMENT OF HEALTH & HUMAN SERVICES

MAY 2 5 2000

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

Katherine M. Wortley, Ph.D.
Senior Regulatory Specialist
ADD Regulatory Affairs
Bldg. AP31, Dept. 9YC
200 Abbott Park Road
Abbott Park, Illinois 60064-6200

Re: K992085
Trade Name: Abbott Imx Glycated Hemoglobin II
Regulatory Class: II
Product Code: LCP
Dated: April 26, 2000
Received: April 27, 2000

Dear Dr. Wortley:

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.

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" (21CFR 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): K992085

Device Name: Abbott IMx® Glycated Hemoglobin II

Indications For Use:

The Abbott IMx® Glycated Hemoglobin II assay is an Ion Capture Assay intended to measure glycated hemoglobin in human anticoagulated whole blood. Measurement of glycated hemoglobin is used in the management of diabetes mellitus.

(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)

(Optional Format 1-2-96)

(Division Sign-Off)
Division of Clinical Laboratory Devices
510(k) Number K992085