

**510(k) Summary**  
**Abbott ARCHITECT™ Glycated Hemoglobin**

**Summary of Safety and Effectiveness Information Supporting a  
Substantially Equivalent Determination**

The following information as presented in the Premarket Notification [510(k)] for Abbott ARCHITECT™ Glycated Hemoglobin constitutes data supporting a substantially equivalent determination.

The ARCHITECT™ Glycated Hemoglobin assay is a Chemiluminescent Microparticle Immunoassay (CMIA) for the quantitative determination of glycated hemoglobin in human anticoagulated whole blood (EDTA, lithium heparin, or sodium heparin). The ARCHITECT™ Glycated Hemoglobin assay is calibrated with Abbott ARCHITECT™ Glycated Hemoglobin Calibrators. Abbott ARCHITECT™ Glycated Hemoglobin Controls are assayed for the verification of the accuracy and precision of the Abbott ARCHITECT™ *i* System.

Substantial equivalence has been demonstrated between the ARCHITECT™ Glycated Hemoglobin assay and the Bio-Rad DIAMAT™ Glycosylated Hemoglobin Analyzer System (K851636). The intended use of the ARCHITECT™ Glycated Hemoglobin assay is for the quantitative determination of glycated hemoglobin in human anticoagulated whole blood using a boronate affinity binding immunoassay. The intended use of the Bio-Rad DIAMAT™ Glycosylated Hemoglobin Analyzer System is for the quantitative determination of glycated hemoglobin in human anticoagulated whole blood using ion exchange high performance liquid chromatography (HPLC).

Sample	Regression Method	n	r	Slope (95%CI)	Intercept (95% CI)
Whole Blood	Least Squares	249	0.961	0.96 (0.93, 1.00)	0.42 (0.15, 0.68)
	Passing-Bablok	249	0.961	1.00 (1.00, 1.06)	0.20 (- 0.27, 0.20)

In this evaluation, human anticoagulated whole blood specimens tested ranged from 4.3 to 14.3 %A1c *eq* with the ARCHITECT™ Glycated Hemoglobin assay and from 4.4 to 14.5 %A1c with the Bio-Rad DIAMAT™ Glycosylated Hemoglobin Analyzer System.

In conclusion, these data demonstrate that the ARCHITECT™ Glycated Hemoglobin assay is as safe and effective as, and is substantially equivalent to, the Bio-Rad DIAMAT™ Glycosylated Hemoglobin Analyzer System.

Prepared and Submitted April 27, 1999 by:

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DEPARTMENT OF HEALTH & HUMAN SERVICES

NOV - 1 1999

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Re: K991483  
Trade Name: Abbott ARCHITECT™ Glycated Hemoglobin  
Regulatory Class: II  
Product Code: LCP  
Dated: August 2, 1999  
Received: August 3, 1999

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.

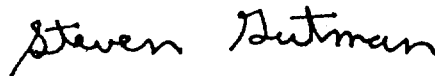
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Under the Clinical Laboratory Improvement Amendments of 1988 (CLIA-88), this device may require a CLIA complexity categorization. To determine if it does, you should contact the Centers for Disease Control and Prevention (CDC) at (770) 488-7655.

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"(21 CFR 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 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): K991483

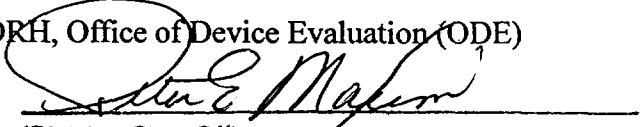
Device Name: Abbott ARCHITECT™ Glycated Hemoglobin

Indications For Use:

The Abbott ARCHITECT™ Glycated Hemoglobin assay is a boronate affinity binding assay intended to measure glycated hemoglobin in human anticoagulated whole blood. Measurement of glycated hemoglobin is used for 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)



(Division Sign-Off)  
Division of Clinical Laboratory Devices  
510(k) Number K991483

Prescription Use

OR Over-The-Counter Use

(Per 21 CFR 801.109)  
(Optional Format 1-2-96)