K992710

NOV 24 1999

# 510(k) Summary
# Abbott ARCHITECT® Glycated Hemoglobin MasterCheck™

## 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 MasterCheck™ constitutes information supporting a substantially equivalent determination.

Abbott ARCHITECT® Glycated Hemoglobin MasterCheck™ is an assayed control for the verification of calibration linearity and reportable range of the ARCHITECT® Glycated Hemoglobin assay on the Abbott ARCHITECT® *i* System.

Substantial equivalence has been demonstrated between the ARCHITECT® Glycated Hemoglobin MasterCheck™ and the Bio-Rad Lyphochek® Diabetes Control Level 1 and 2. The intended use of the ARCHITECT® Glycated Hemoglobin MasterCheck™ is for use in the verification of calibration linearity and reportable range of the Glycated Hemoglobin assay on the Abbott ARCHITECT® *i* system. The intended use of the Bio-Rad Lyphochek® Diabetes Control Level 1 and 2 is monitoring the precision of laboratory testing procedures.

In conclusion, the information demonstrates that the ARCHITECT® Glycated Hemoglobin MasterCheck™ is as safe and effective as, and is substantially equivalent to the Bio-Rad Lyphochek® Diabetes Control Level 1 and 2.

Prepared and Submitted August 10, 1999, edited November 5, 1999 by:

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DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
2098 Gaither Road
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Re: K992710
Trade Name: Abbott ARCHITECT™ Glycated Hemoglobin MasterCheck™
Regulatory Class: I
Product Code: JJY
Dated: November 5, 1999
Received: November 8, 1999

Dear Dr. Wortely:

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.

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 at (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/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 K992710

Device Name: Abbott ARCHITECT® Glycated Hemoglobin MasterCheck™

Indications For Use:

The Abbott ARCHITECT® Glycated Hemoglobin MasterCheck™ is an assayed control intended for use in the verification of calibration linearity and reportable range of the Glycated Hemoglobin assay on the Abbott ARCHITECT® *i* system.

(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 K992710

Prescription Use ✓ OR Over-The-Counter Use ____

(Per 21 CFR 801.109)

(Optional Format 1-2-96)