K983424

DEC 1 1998

510(k) Summary
Abbott ARCHITECT™ Total β-hCG

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™ Total β-hCG constitutes data supporting a substantially equivalent determination.

ARCHITECT Total β-hCG is a Chemiluminescent Microparticle Immunoassay (CMIA) for the quantitative and qualitative determination of β-hCG in human serum and plasma (lithium heparin, sodium heparin, or potassium EDTA) for the early detection of pregnancy. ARCHITECT Total β-hCG is calibrated with ARCHITECT Total β-hCG Calibrators. ARCHITECT Total β-hCG Controls are assayed to verify the accuracy and precision of the Abbott ARCHITECT *i* System.

Substantial equivalence has been demonstrated between the ARCHITECT Total β-hCG assay and the AxSYM® Total β-hCG assay. The intended use of both assays is for the quantitative and qualitative determination of beta-human chorionic gonadotropin (β-hCG) for the early detection of pregnancy. Both assays are automated, *in vitro* immunoassays that use antibodies specific for β-hCG. A least squares linear regression analysis between these two assays, using 337 specimens over a range of 2.0 to 15,000 mIU/mL, yielded a correlation coefficient of 0.987, slope of 0.82 (95% confidence interval [CI] of 0.81 to 0.84), and y-axis intercept of 58.29 mIU/mL (95% CI of –11.67 to 128.26). A Passing-Bablok linear regression analysis between these two assays, using 337 specimens over a range of 2.0 to 15,000 mIU/mL, yielded a correlation coefficient of 0.987, slope of 0.88 mIU/mL (95% CI of 0.86 to 0.90), and y-axis intercept of 4.36 mIU/mL (95% CI of 2.47 to 7.06).

In conclusion, these data demonstrate that the ARCHITECT Total β-hCG assay is as safe and effective as, and is substantially equivalent to, the AxSYM Total β-hCG assay.

Prepared and Submitted September 28, 1998, by:
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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
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ABBOTT LABORATORIES
200 Abbott Park Road
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Re: K983424
Trade Name: Abbott ARCHITECT™ Total β-hCG
Regulatory Class: II
Product Code: 75 DHA
Dated: November 16, 1998
Received: November 17, 1998

Dear Ms. Gates:

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"(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 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): K983424

Device Name: Abbott ARCHITECT™ Total β-hCG

Indications For Use:

Abbott ARCHITECT™ Total β-hCG is a Chemiluminescent Microparticle Immunoassay (CMIA) for the quantitative and qualitative determination of beta-human chorionic gonadotropin (β-hCG) in human serum and plasma on the Abbott ARCHITECT *i* System for the early detection of pregnancy.

(Division Sign-Off)
Division of Clinical Laboratory Devices
510(k) Number K983424

(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)