K990774

MAY 11 1999

510(k) Summary
Abbott ARCHITECT™ CEA

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 CEA constitutes data supporting a substantially equivalent determination.

ARCHITECT CEA is a Chemiluminescent Microparticle Immunoassay for the quantitative determination of CEA in human serum and plasma. ARCHITECT CEA is calibrated with ARCHITECT CEA Calibrators. ARCHITECT CEA 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 CEA assay and the Abbott AxSYM® CEA assay, a microparticle enzyme immunoassay. The intended use of both assays is for the quantitative determination of CEA in human serum and plasma, and to be used as an aid in the prognosis and management of cancer patients in whom changing concentrations of CEA are observed. Both assays use the same mouse monoclonal antibodies. A least squares correlation analysis between these two assays, using 1,069 specimens, yielded a correlation coefficient of 0.991, slope of 0.92 (95% confidence interval of 0.91 to 0.93), and y-intercept of 0.85 ng/mL (95% confidence interval of 0.01 to 1.69). A Passing-Bablok correlation analysis, using 1,069 specimens, yielded a correlation coefficient of 0.991, slope of 0.97 (95% confidence interval of 0.96 to 0.98), and y-intercept of 0.28 ng/mL (95% confidence interval of 0.26 to 0.30). Both assays show similar distribution of CEA concentrations across various conditions. Both assays also show similar trending when monitoring patients in whom changing concentrations of CEA are observed.

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

Prepared and Submitted March 8, 1999 by:

Karen L. Gates, M.S.
Senior Regulatory Specialist
ADD Regulatory Affairs
1-847-938-0538

Abbott Laboratories
200 Abbott Park Road
Abbott Park, IL 60064

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

MAY 11 1999

Ms. Karen L. Gates, M.S.
Senior Regulatory Specialist
ADD Regualtory Affairs
D9V6 AP31
200 Abbott Park Road
Abbott Park, Illinois 60064-3537

Re: K990774
Trade Name: Abbott ARCHITECT™ CEA
Regulatory Class: II
Product Code: DHX
Dated: March 8, 1999
Received: March 9, 1999

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.

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 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): K990774

Device Name: Abbott ARCHITECT™ CEA

Indications For Use:

The ARCHITECT CEA assay is a Chemiluminescent Microparticle Immunoassay (CMIA) for the quantitative determination of Carcinoembryonic Antigen (CEA) in human serum and plasma on the ARCHITECT *i* System. The ARCHITECT CEA assay is to be used as an aid in the prognosis and management of cancer patients in whom changing concentrations of CEA are observed.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NECESSARY)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Clinical Laboratory Devices
510(k) Number K990774

Prescription Use ✓ OR Over-The-Counter Use____
(Per 21 CFR 801.109)

(Optional Format 1-2-96)