NOV - 4 199 K964185

510(k) SUMMARY
IMx® CA 125™

SUMMARY OF SAFETY AND EFFECTIVENESS INFORMATION SUPPORTING A SUBSTANTIALLY EQUIVALENT DETERMINATION

The following information as presented in the Premarket Notification [510(k)] for IMx CA 125 constitutes data supporting a substantially equivalent determination.

IMx CA 125 is a microparticle enzyme immunoassay on the IMx System for the quantitative measurement of CA 125 assay values in human serum. IMx CA 125 employs Abbott Calibrators and Controls.

Substantial equivalence has been demonstrated between the Abbott IMx CA 125 assay and the ABBOTT CA 125 II™ RIA assay. IMx CA 125 is intended to be used as an aid in monitoring the response to therapy of epithelial ovarian cancer patients while the CA 125 II RIA is intended to be used as an aid in the detection of residual ovarian carcinoma in patients who have undergone first line therapy and would be considered for diagnostic second look procedures. Both assay intended uses reflect a monitoring claim. A linear regression analysis between these two assays, using 493 specimens with IMx CA 125 assay values ranging from 2.0 to 22,821.0 U/mL, yielded a correlation coefficient of 0.997, slope of 0.94, and y-intercept of -4.7 U/mL. The dynamic range of IMx CA 125 is 0 - 600 U/mL with a sensitivity of 2 U/mL. The dynamic range of CA 125 II RIA is 0 - 500 U/mL with a sensitivity of 0.4 U/mL. Receiver Operating Characteristic (ROC) analyses on specimen values from 130 apparently healthy females plus 45 patients with benign gynecologic conditions vs. 197 patients with ovarian cancer gave substantially equivalent areas under the curve of 0.87 for IMx CA 125 and 0.80 for CA 125 II RIA. Using 35 U/mL as the reference value, similar sensitivities of 64.0 and 66.0% and specificities of 96.0 and 92.0% were obtained for IMx CA 125 and CA 125 II RIA, respectively. The concordance at 35 U/mL was 96.2%, 95.6%, 97.0%, and 94.1% for 130 apparently healthy females, 45 patients with benign gynecologic conditions, 197 patients with ovarian cancer, and 542 total subjects, respectively.

Serial tracking data on 55 patients with ovarian cancer showed comparable trending results for both assays. Serial IMx CA 125 results showed good agreement with the clinical status of 39 of the ovarian cancer patients evaluated.

In conclusion, these data demonstrate that the Abbott IMx CA 125 assay is as safe and effective as, and is substantially equivalent to the ABBOTT CA 125 II RIA assay.

Prepared and Submitted October 18, 1996 (edited September 18, 1997) by:

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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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NOV - 4 1997

Re: K964185/S3
Trade Name: ABBOTT IMx® CA 125™
Regulatory Class: II Tier III
Product Code: LTK
Dated: September 18, 1997
Received: September 19, 1997

Dear Ms. Sonsalla:

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 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 requirement, 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 (if known): K964185

Device Name: IMx® CA 125™

Indications for Use:

The IMx® CA 125™ assay is a Microparticle Enzyme Immunoassay (MEIA) for the quantitative measurement of CA 125 assay values in human serum. The IMx® CA 125™ assay is to be used as an aid in monitoring response to therapy for patients with epithelial ovarian cancer. Serial testing for patient CA 125 assay values should be used in conjunction with other clinical methods used for monitoring ovarian cancer.

Peter E. Maddux

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

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

Concurrence of CDRH, Office of DeviceEvaluation (ODE)

Perscription Use ✓ OR Over-The-Counter Use _____
(Per 21CFR 801.109)

(Optional Format 1-2-96)