K963926

SEP 15 1997

510(k) SUMMARY
AxSYM® CA 15-3™

SUMMARY OF SAFETY AND EFFECTIVENESS INFORMATION SUPPORTING A SUBSTANTIALLY EQUIVALENT DETERMINATION

The following information as presented in the Premarket Notification [510(k)] for AxSYM CA 15-3 constitutes data supporting a substantially equivalent determination.

AxSYM CA 15-3 is a microparticle enzyme immunoassay for the quantitative measurement of CA 15-3 assay values in human serum and EDTA plasma on the AxSYM System. AxSYM CA 15-3 employs Abbott Calibrators and Controls.

Substantial equivalence has been demonstrated between the Abbott AxSYM® CA 15-3™ assay and the BIOMIRA Diagnostics Inc. TRUQUANT® BR™ RIA assay. Both assays are intended to be used as an aid in the management of stage II and stage III breast cancer patients. A linear regression analysis between these two assays, using 560 specimens with AxSYM CA 15-3 assay values ranging from 4.0 to 248.7 U/mL, yielded a correlation coefficient of 0.888, slope of 0.67, and y-intercept of 4.2 U/mL. The dynamic range of AxSYM CA 15-3 is 0 - 250 U/mL with an analytical sensitivity of 0.3 U/mL. The dynamic range of TRUQUANT BR RIA is 0 - 200 U/mL with an analytical sensitivity of 7.0 U/mL. Receiver Operator Characteristic (ROC) analyses on 160 apparently healthy females plus 30 benign breast patients vs. 228 malignant breast patients gave essentially equivalent areas under the curve of 0.69 for AxSYM CA 15-3 and 0.70 for TRUQUANT BR RIA. Serial tracking data on 24 malignant breast patients showed comparable trending results for both assays.

Seventy nine stage II and stage III breast cancer patients were evaluated in a blinded study using the AxSYM CA 15-3 assay and the TRUQUANT BR RIA. 359 specimens from 77 of the evaluable patients gave a concordance (agreement) between the two assays of 91% at their respective reference values. At the claimed reference values for the assays (31.3 U/mL for AxSYM CA 15-3 and 37.7 U/mL for TRUQUANT BR RIA), when using values obtained within 6 months of relapse, similar sensitivities of 54% (95% CI=25-81) and 62% (95% CI=32-86) and specificities of 94% (95% CI=85-99) and 91% (95% CI=80-97) were obtained for AxSYM CA 15-3 and TRUQUANT BR RIA, respectively.

In conclusion, these data demonstrate that the Abbott AxSYM CA 15-3 assay is as safe and effective as, and is substantially equivalent to the BIOMIRA Diagnostics Inc. TRUQUANT BR RIA assay.

Prepared and Submitted September 26, 1996 (edited September 10, 1997) by:

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SEP 15 1997

Re: K963926/S002
Trade Name: Abbott AxSYM® CA 15-3™
Regulatory Class: II
Product Code: MOI
Dated: July 15, 1997
Received: July 16, 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 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 (if known): K963926

Device Name: AxSYM CA 15-3

Indications For Use:

The AxSYM® CA 15-3™ assay is a Microparticle Enzyme Immunoassay (MEIA) for the quantitative measurement of CA 15-3 assay values in human serum and plasma (EDTA) to aid in the management of breast cancer patients. Serial testing for patient CA 15-3 assay values should be used in conjunction with other clinical methods for monitoring breast cancer.

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

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Peter E Mason

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

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

(Optional Format 1-2-96)