

K981060

APR 29 1998

**510(k) Summary**  
**Abbott AxSYM® 3rd Generation TSH**

**Summary of Safety and Effectiveness Information Supporting a  
Substantially Equivalent Determination**

The following information as presented in the Premarket Notification [510(k)] for the Abbott AxSYM® 3rd Generation TSH constitutes data supporting a substantially equivalent determination.

AxSYM 3rd Generation TSH is a Microparticle Enzyme Immunoassay (MEIA) for the quantitative determination of TSH in human serum or plasma. AxSYM 3rd Generation TSH is calibrated with Abbott AxSYM 3rd Generation TSH Calibrators. Abbott AxSYM 3rd Generation TSH Controls are assayed for the verification of the accuracy and precision of the AxSYM System.

Substantial equivalence has been demonstrated between the AxSYM 3rd Generation TSH assay and the AxSYM Ultrasensitive hTSH II assay. The intended use of both assays is for the quantitative determination of TSH in human serum or plasma. Both assays are automated, *in vitro* immunoassays that use antibodies specific for TSH. The fluorescent signal measured by both assays is directly related to the concentration of TSH in the sample. The Least Squares regression analysis between these two assays, using 921 specimens, yielded a Pearson correlation coefficient of 0.977, slope of 1.033 (95% confidence interval of 1.018, 1.047), and Y-axis intercept of 0.538  $\mu$ IU/mL (95% confidence interval of 0.387, 0.690).

In conclusion, these data demonstrate that the AxSYM 3rd Generation TSH assay is as safe and effective as, and is substantially equivalent to, the AxSYM Ultrasensitive hTSH II assay.

Prepared and Submitted March 20, 1998 by:

April Veoukas  
Senior Regulatory Specialist  
ADD Regulatory Affairs  
(847) 937-8197  
Abbott Laboratories  
200 Abbott Park Road  
Abbott Park, IL 60064-3537



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration  
2098 Gaither Road  
Rockville MD 20850

APR 29 1998

April Veoukas, J.D.  
Senior Regulatory Specialist  
Abbott Laboratories  
200 Abbott Park Road, Dept. 9V6, Bldg. AP31  
Abbott Park, Illinois 60064-3537

Re: K981060  
Abbott AxSYM® 3<sup>rd</sup> Generation TSH  
Regulatory Class: I & II  
Product Code: JLW, JIS, JJX  
Dated: March 20, 1998  
Received: March 23, 1998

Dear Ms. Veoukas:

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 (Pre-market 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 pre-market 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.

Page 2

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/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): \_\_\_\_\_

Device Name: Abbott AxSYM® 3rd Generation TSH

Indications For Use:

AxSYM® 3rd Generation TSH is a Microparticle Enzyme Immunoassay (MEIA) for the quantitative determination of thyroid stimulating hormone (TSH) in human serum or plasma on the AxSYM System. The AxSYM 3rd Generation TSH assay is used as an aid in the assessment of thyroid status, diagnosis of thyroid disease, and treatment of thyroid disease.

  
\_\_\_\_\_  
(Division Sign Off)  
Division of Clinical Laboratory Devices  
510(k) Number k981060

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

\_\_\_\_\_  
Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use   
(Per 21 CFR 801.109)

OR

Over-The-Counter Use \_\_\_\_\_  
(Optional Format 1-2-96)