

510(k) Summary
Abbott ARCHITECT™ TSH
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™ TSH constitutes data supporting a substantially equivalent determination.

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

Substantial equivalence has been demonstrated between the ARCHITECT TSH and the AxSYM® Ultrasensitive hTSH assay. The intended use of both assays is for the quantitative determination of human thyroid stimulating hormone (TSH). Both assays can be performed with human serum and plasma (lithium heparin, sodium heparin, or potassium EDTA). The least squares linear regression analysis between these two assays, using 534 specimens, yielded a correlation coefficient of 0.987, slope of 0.96 (95% confidence interval of 0.95 to 0.98), and y-axis intercept of -0.7135 μ IU/mL (95% confidence interval of -1.1931 to -0.2339). The Passing-Bablok linear regression analysis between these two assays, using 534 specimens, yielded a correlation coefficient of 0.987, slope of 0.91 (95% confidence interval of 0.90 to 0.92), and y-axis intercept of 0.0098 μ IU/mL (95% confidence interval of 0.0019 to 0.0162).

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

Prepared and Submitted September 29, 1998 by:

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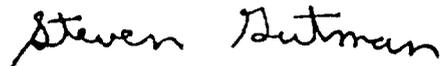
Abbott Laboratories
200 Abbott Park Road
Abbott Park, IL 60064-3537

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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 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): K98342

Device Name: Abbott ARCHITECT™ TSH

Indications For Use:

Abbott ARCHITECT™ TSH is a Chemiluminescent Microparticle Immunoassay (CMIA) for the quantitative determination of thyroid stimulating hormone (TSH) in human serum and plasma. The ARCHITECT TSH assay is to be used as an aid in the assessment of thyroid status, diagnosis of thyroid disease, and treatment of thyroid disease.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)

Division of Clinical Laboratory Devices

510(k) Number K98342

Prescription Use
(Per 21 CFR 801.109)

OR Over-The-Counter Use

(Optional Format 1-2-96)