

NOV 25 1998

1C983 440

**510(k) Summary**  
**Abbott ARCHITECT™ Total T<sub>4</sub>**

**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™ Total T<sub>4</sub> constitutes data supporting a substantially equivalent determination.

ARCHITECT Total T<sub>4</sub> is a Chemiluminescent Microparticle Immunoassay (CMIA) for the quantitative determination of total T<sub>4</sub> in human serum or plasma (lithium heparin, sodium heparin, or potassium EDTA). ARCHITECT Total T<sub>4</sub> is calibrated with ARCHITECT Total T<sub>4</sub> Calibrators. ARCHITECT Total T<sub>4</sub> 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 Total T<sub>4</sub> assay and the AxSYM® Total T<sub>4</sub> assay. The intended use of both assays is for the quantitative determination of total T<sub>4</sub> in human serum and plasma. Least squares linear regression analysis of an ARCHITECT Total T<sub>4</sub> vs. AxSYM Total T<sub>4</sub> comparison, using 1155 specimens, gave the following parameter estimates: correlation coefficient = 0.928, slope = 1.01 and y-axis intercept = -0.11 µg/dL. Passing-Bablok linear regression analysis of an ARCHITECT Total T<sub>4</sub> vs. AxSYM Total T<sub>4</sub> comparison, using 1155 specimens, gave the following parameter estimates: correlation coefficient = 0.928, slope = 0.99 and y-axis intercept = -0.13 µg/dL.

In conclusion, these data demonstrate that the ARCHITECT Total T<sub>4</sub> assay is as safe and effective as, and is substantially equivalent to, the AxSYM Total T<sub>4</sub> assay.

Prepared and Submitted September 28, 1998 by:

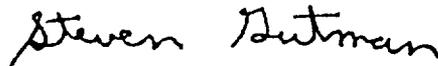
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This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device 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): K983440

Device Name: Abbott ARCHITECT™ Total T<sub>4</sub>

Indications For Use:

The ARCHITECT™ Total T<sub>4</sub> (TT<sub>4</sub>) assay is a Chemiluminescent Microparticle Immunoassay (CMIA) for the quantitative determination of thyroxine (total T<sub>4</sub>) in human serum and plasma. The ARCHITECT Total T<sub>4</sub> assay is to be used as an aid in the assessment of thyroid status.

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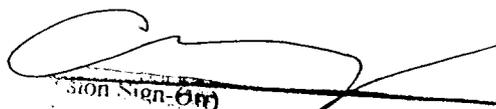
Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use   
(Per 21 CFR 801.109)

OR

Over-The-Counter Use

(Optional Format 1-2-96)

  
510(k) Number K983440  
Medical Laboratory Devices