

**510(k) Summary**  
**Abbott ARCHITECT™ Total T<sub>3</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>3</sub> constitutes data supporting a substantially equivalent determination.

ARCHITECT Total T<sub>3</sub> is a Chemiluminescent Microparticle Immunoassay (CMIA) for the quantitative determination of total T<sub>3</sub> in human serum and plasma (lithium heparin, sodium heparin or potassium EDTA). ARCHITECT Total T<sub>3</sub> is calibrated with ARCHITECT Total T<sub>3</sub> Calibrators. ARCHITECT Total T<sub>3</sub> Controls are assayed for verification of the accuracy and precision of the Abbott ARCHITECT *i* System.

Substantial equivalence has been demonstrated between the ARCHITECT Total T<sub>3</sub> assay and the AxSYM® Total T<sub>3</sub> assay. The intended use of both assays is for the quantitative determination of total T<sub>3</sub> in human serum and plasma. Least squares linear regression analysis of an ARCHITECT Total T<sub>3</sub> vs. AxSYM Total T<sub>3</sub> comparison, using 1120 specimens, gave the following parameter estimates: correlation coefficient = 0.950, slope = 0.86 and y-axis intercept = 0.22 ng/mL. Passing-Bablok linear regression analysis of an ARCHITECT Total T<sub>3</sub> vs. AxSYM Total T<sub>3</sub> comparison, using 1120 specimens, gave the following parameter estimates: correlation coefficient = 0.950, slope = 1.08 and y-axis intercept = -0.04 ng/mL.

In conclusion, these data demonstrate that the ARCHITECT Total T<sub>3</sub> assay is as safe and effective as, and is substantially equivalent to, the AxSYM Total T<sub>3</sub> assay.

Prepared and Submitted September 28, 1998 by:

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Food and Drug Administration  
2098 Gaither Road  
Rockville MD 20850

Re: K983434  
Trade Name: Abbott ARCHITECT™ Total T<sub>3</sub>  
Regulatory Class: II           Product Code: CDP  
                                  II                                    JIT  
                                  I                                     JJX  
Dated: September 28, 1998  
Received: September 29, 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 legally marketed predicate 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.

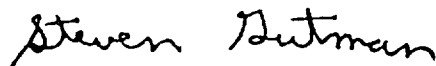
If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially 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.

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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): K983434

Device Name: Abbott ARCHITECT™ Total T<sub>3</sub>

Indications For Use:

The ARCHITECT™ Total T<sub>3</sub> (TT<sub>3</sub>) assay is a Chemiluminescent Microparticle Immunoassay (CMIA) for the quantitative determination of total triiodothyronine (total T<sub>3</sub>) in human serum and plasma. The ARCHITECT Total T<sub>3</sub> assay is to be used as an aid in the assessment of thyroid status.

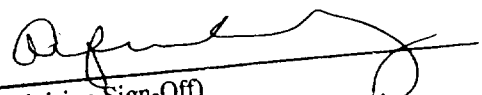
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\_\_\_\_\_ Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use   
(Per 21 CFR 801.109)

OR

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

  
\_\_\_\_\_  
(Division Sign-Off)  
Division of Clinical Laboratory Devices  
510(k) Number K983434