

NOV 20 1998

K 983417

**510(k) Summary**  
**Abbott ARCHITECT™ Free 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™ Free T<sub>4</sub> constitutes data supporting a substantially equivalent determination.

ARCHITECT Free T<sub>4</sub> is a Chemiluminescent Microparticle Immunoassay (CMIA) for the quantitative determination of free T<sub>4</sub> in human serum or plasma (lithium heparin, sodium heparin or potassium EDTA). ARCHITECT Free T<sub>4</sub> is calibrated with ARCHITECT Free T<sub>4</sub> Calibrators. ARCHITECT Free 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 Free T<sub>4</sub> assay and the AxSYM® Free T<sub>4</sub> assay. The intended use of both assays is for the quantitative determination of free T<sub>4</sub> in human serum and plasma. Least squares linear regression analysis of an ARCHITECT Free T<sub>4</sub> vs. AxSYM Free T<sub>4</sub> comparison, using 1250 specimens, gave the following parameter estimates: correlation coefficient = 0.932, slope = 0.81 and y-axis intercept = 0.23 ng/dL. Passing-Bablok linear regression analysis of an ARCHITECT Free T<sub>4</sub> vs. AxSYM Free T<sub>4</sub> comparison, using 1250 specimens, gave the following parameter estimates: correlation coefficient = 0.932, slope = 0.98 and y-axis intercept = 0.01 ng/dL.

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

Prepared and Submitted September 28, 1998 by:

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2098 Gaither Road  
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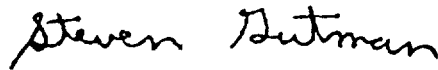
If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially 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.

Page 2

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,

A handwritten signature in black ink that reads "Steven Gutman". The signature is written in a cursive, slightly slanted style.

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): K983417

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

Indications For Use:

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

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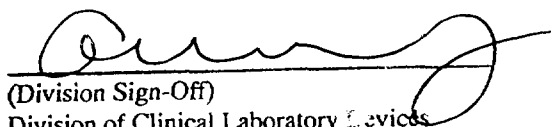
\_\_\_\_\_  
Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ☒  
(Per 21 CFR 801.109)

OR

Over-The-Counter Use \_\_\_\_\_

(Optional Format 1-2-96)

  
(Division Sign-Off)  
Division of Clinical Laboratory Devices

510(k) Number K983417