

510(k) Summary
Abbott ARCHITECT™ Testosterone

**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™ Testosterone constitutes data supporting a substantially equivalent determination.

ARCHITECT Testosterone is a Chemiluminescent Microparticle Immunoassay (CMIA) for the quantitative determination of testosterone in human serum and plasma (lithium heparin, sodium heparin or potassium EDTA). ARCHITECT Testosterone is calibrated with Abbott ARCHITECT Testosterone Calibrators. Abbott ARCHITECT Testosterone 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 Testosterone assay and the Chiron Diagnostics ACS:180® Testosterone assay. The intended use of the ARCHITECT Testosterone assay is for the quantitative determination of testosterone in human serum and plasma. The intended use of the Chiron Diagnostics ACS:180 Testosterone assay is for the quantitative determination of total testosterone (bound and unbound) in serum. Both assay are competitive immunoassays that use antibodies specific for testosterone and are performed on fully automated immunoassay systems. A least squares linear regression analysis between these two assays, using 607 specimens, yielded a correlation coefficient of 0.986, slope of 0.89 (95% Confidence Interval [CI] of 0.88 to 0.90), and y-axis intercept of -0.02 ng/mL (95% CI of -0.08 to 0.04).

In conclusion, these data demonstrate that the ARCHITECT Testosterone assay is as safe and effective as, and is substantially equivalent to, the Chiron Diagnostics ACS:180 Testosterone assay.

Prepared and Submitted September 11, 1998, by:

Karen L. Gates, M.S.

Sr. Regulatory Specialist

ADD Regulatory Affairs

(847) 938-0538

Abbott Laboratories

200 Abbott Park Road

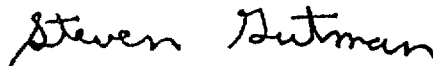
Abbott Park, IL 60064-3537

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,



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): K983212

Device Name: Abbott ARCHITECT™ Testosterone

Indications For Use:

Abbott ARCHITECT Testosterone is a Chemiluminescent Microparticle Immunoassay (CMIA) for the quantitative determination of testosterone in human serum and plasma on the Abbott ARCHITECT *i* System. Measurements of testosterone are used in the diagnosis and treatment of disorders involving the male sex hormones (androgens), including primary and secondary hypogonadism, delayed or precocious puberty, impotence in males and, in females, hirsutism (excessive hair) and virilization (masculinization) due to tumors, polycystic ovaries, and adrenogenital syndromes.


(Division Sign-Off)
Division of Clinical Laboratory Devices
510(k) Number K983212

(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)