K983212

NOV 18 1998

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:
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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
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NOV 18 1998

Re: K983212
Trade Name: Abbott ARCHITECT™ Testosterone

Regulatory Class:	Product Code:
I	CDZ
II	JIS
I	JJX
I	JJE

Dated: September 11, 1998
Received: September 14, 1998

Dear Ms. Gates:

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.

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 Gutman

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 ✓ OR Over-The-Counter Use____
(Per 21 CFR 801.109)

(Optional Format 1-2-96)