K041687

AUG 18 2004

510(k) Summary
Abbott Immunoassay/Clinical Chemistry Single Analyte Quality Control Materials (assayed) and Abbott ARCHITECT® Estradiol Calibrators

Summary of Safety and Effectiveness Information Supporting a Substantially Equivalent Determination

Name of Submitter:
Abbott Laboratories
100 Abbott Park Road
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Contact Person:
Kent Smith
Sr. Regulatory Affairs Specialist
ADD Regulatory Affairs
(847) 938-4807
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Date of Preparation of 510(k) Summary: June 21, 2004

Trade Name(s):

Trade Name	Common Name	Device Classification	Classification Panel	Product Code	Regulation Number
Abbott ARCHITECT® Estradiol Controls (LN 6C22)	Single Analyte QC Material (assayed)	Class I	Clinical Chemistry (75)	JJX	862.1660
Abbott ARCHITECT® Estradiol Controls (LN 2K25)	Single Analyte QC Material (assayed)	Class I	Clinical Chemistry (75)	JJX	862.1660
Abbott AxSYM® Estradiol Controls	Single Analyte QC Material (assayed)	Class I	Clinical Chemistry (75)	JJX	862.1660
Abbott FSH Controls	Single Analyte QC Material (assayed)	Class I	Clinical Chemistry (75)	JJX	862.1660
Abbott ARCHITECT® LH Controls	Single Analyte QC Material (assayed)	Class I	Clinical Chemistry (75)	JJX	862.1660

Trade Name	Common Name	Device Classification	Classification Panel	Product Code	Regulation Number
Abbott ARCHITECT® Prolactin Controls	Single Analyte QC Material (assayed)	Class I	Clinical Chemistry (75)	JJX	862.1660
Abbott ARCHITECT® Progesterone Controls	Single Analyte QC Material (assayed)	Class I	Clinical Chemistry (75)	JJX	862.1660
Abbott ARCHITECT® Estradiol Calibrators	Calibrator	Class II	Clinical Chemistry (75)	JIT	862.1150

Device Description:

Abbott Immunoassay/Clinical Chemistry Single Analyte Quality Control Materials (assayed) are devices intended for medical purposes for use in Abbott test systems to estimate test precision and to detect systematic analytical deviations that are used in the quantitative determination of values in the measurement of substances in human specimens.

Abbott ARCHITECT® Estradiol Calibrators are devices intended for medical purposes for use in Abbott assay test systems to establish points of reference that are used in the quantitative determination of values in the measurement of substances in human specimens.

Conclusion:

Substantial equivalence is claimed to the legally marketed device as presented in the table below. In addition substantial equivalence has been demonstrated via the use of the FDA Guidance for Industry "Points to Consider Guidance Document on Assayed and Unassayed Quality Control Material" draft guidance released for comment on February 3, 1999 for the Abbott Immunoassay/Clinical Chemistry Single Analyte Quality Control Materials (assayed) and "Abbreviated 510(k) Submissions for In Vitro Diagnostic Calibrators" issued on February 22, 1999 for the Abbott ARCHITECT® Estradiol Controls.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

AUG 1 8 2004

Mr. Kent Smith
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Abbott Diagnostic Division
ADD Regulatory Affairs
D-09VA, Building AP6C
100 Abbott Park Road
Abbott Park, IL 60064-3500

Re: k041687
Trade/Device Name: Abbott ARCHITECT® Estradiol Controls (LN 6C22)
Abbott ARCHITECT® Estradiol Controls (LN 2K25
Abbott AxSYM® Estradiol Controls
Abbott FSH Controls
Abbott ARCHITECT® LH Controls
Abbott ARCHITECT® Prolactin Controls
Abbott ARCHITECT® Progesterone Controls
Abbott ARCHITECT® Estradiol Calibrators
Regulation Number: 21 CFR 862.1150
Regulation Name: Calibrator
Regulatory Class: Class II
Product Code: JIT, JJX
Dated: July 26, 2004
Received: July 27, 2004

Dear Mr. Smith:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and 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) that do not require approval of a premarket approval application (PMA). 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 (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820).

This letter will allow you to begin marketing your device as described in your Section 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 information about the application of labeling requirements to your device, or questions on the promotion and advertising of your device, please contact the Office of *In Vitro* Diagnostic Device Evaluation and Safety at (301) 594-3084. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer 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,

Jean M. Cooper MS, DVM.

Jean M. Cooper, MS, D.V.M.
Director
Division of Chemistry and Toxicology
Office of *In Vitro* Diagnostic Device
Evaluation and Safety
Center for Devices and
Radiological Health

Enclosure

Indications for Use:

510(k) Number (if known): K041687

Device Name: Abbott ARCHITECT® Estradiol Controls (LN 6C22)
Abbott ARCHITECT® Estradiol Controls (LN 2K25)
Abbott AxSYM® Estradiol Controls
Abbott FSH Controls
Abbott ARCHITECT® LH Controls
Abbott ARCHITECT® Prolactin Controls
Abbott ARCHITECT® Progesterone Controls
Abbott ARCHITECT® Estradiol Calibrators

Indications For Use:

Abbott ARCHITECT® Estradiol Controls (LN 6C22) are devices intended for use in the ARCHITECT® Estradiol assay test system to estimate test precision and to detect systematic analytical deviations that are used in the quantitative determination of estradiol in human specimens. Estradiol measurements are used in the diagnosis and treatment of various hormonal sexual disorders and in assessing placental function in complicated pregnancy.

Abbott ARCHITECT® Estradiol Controls (LN 2K25) are devices intended for use in the ARCHITECT® Estradiol assay test system to estimate test precision and to detect systematic analytical deviations that are used in the quantitative determination of estradiol in human specimens. Estradiol measurements are used in the diagnosis and treatment of various hormonal sexual disorders and in assessing placental function in complicated pregnancy.

Abbott AxSYM® Estradiol Controls are devices intended for use in the AxSYM® Estradiol assay test system to estimate test precision and to detect systematic analytical deviations that are used in the quantitative determination of estradiol in human specimens. Estradiol measurements are used in the diagnosis and treatment of various hormonal sexual disorders and in assessing placental function in complicated pregnancy.

Abbott FSH Controls are devices intended for use in the ARCHITECT, AxSYM, and IMx FSH assay test systems to estimate test precision and to detect systematic analytical deviations that are used in the quantitative determination of follicle-stimulating hormone (FSH) in human specimens. FSH measurements are used in the diagnosis and treatment of pituitary gland and gonadal disorders

Abbott ARCHITECT® LH Controls are devices intended for use in the ARCHITECT LH assay test system to estimate test precision and to detect systematic analytical deviations that are used in the quantitative determination of luteinizing hormone (LH) in human specimens. LH measurements are used in the diagnosis and treatment of gonadal function.

Abbott ARCHITECT® Prolactin Controls are devices intended for use in the ARCHITECT Prolactin assay test system to estimate test precision and to detect systematic analytical deviations that are used in the quantitative determination of prolactin in human specimens. Prolactin measurements are used in the diagnosis and treatment of disorders of the anterior pituitary gland or of the hypothalamus portion of the brain.

Abbott ARCHITECT® Progesterone Controls are devices intended for use in the ARCHITECT® Progesterone assay test system to estimate test precision and to detect systematic analytical deviations that are used in the quantitative determination of progesterone in human specimens. Progesterone measurements are used in the diagnosis and treatment of disorders of the ovaries or placenta.

Abbott ARCHITECT® Estradiol Calibrators are devices intended for use in the ARCHITECT® Estradiol assay test system to establish points of reference that are used in the quantitative determination of estradiol in human specimens. Estradiol measurements are used in the diagnosis and treatment of various hormonal sexual disorders and in assessing placental function in complicated pregnancy.

Prescription Use ✓ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

Division Sign-Off

Office of In Vitro Diagnostic
Device Evaluation and Safety

510(k) K041687