K984604

BIO-RAD **Bio-Rad Laboratories**

Diagnostics Group
9500 Jeronimo Road
Irvine, California 92618-2017
Telephone: (949) 598-1200

510(k) Summary

Submitter
Bio-Rad Laboratories
9500 Jeronimo Road
Irvine, CA
(949)598-1285
Fax (949)598-1555

Contact Person
Elizabeth Platt

Date of Summary Preparation
December 21, 1998

Device (Trade & Common Name)
Architect Estradiol MasterCheck

Classification Name
Class I, 75JJX
CFR 862.1660: Single (Specified) Analyte Controls (Assayed and Unassayed)

Devices to Which Substantial Equivalence is Claimed
Document Serum Multi-Analyte Verification Test Set
Casco Standards
Yarmouth, ME
K950469

Statement of Intended Use
Architect Estradiol MasterCheck is intended for use in the verification of sensitivity, calibration linearity, and reportable range of the Estradiol assay on the Abbott Architect *i* System.

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Description of the Device

Architect Estradiol MasterCheck Level 0 contains TRIS buffer with protein (bovine) stabilizers.
Architect Estradiol MasterCheck Levels 1, 2, 3 and 4 contain estradiol prepared in TRIS buffer with protein (bovine) stabilizers.
Preservative: Antimicrobial Agent.

Statement of How Technological Characteristics Compare to Substantial Equivalence Device

A table is provided below comparing the similarities between the Bio-Rad Architect Estradiol MasterCheck and the devices to which substantial equivalence is claimed.

	Architect Estradiol MasterCheck	Casco Standards Document Serum Multi-Analyte Verification Test Set
Intended Use	Verification of sensitivity, calibration linearity, and reportable range of the Estradiol assay on the Abbott Architect *i* System.	*In vitro* diagnostic use in the quantitative determination of linearity, calibration verification and verification of reportable range using automated, semi-automated and manual methods.
Form	Liquid	Liquid
Matrix	TRIS buffer with protein (bovine) stabilizers.	Human Serum
Storage	2-8°C	-10 to -20°C
Analytes	Estradiol	Multiple
Open Vial Claim	3 Days at 2-8°C.	30 Days at 2-8°C.
Differences	Calibration verifier for the Architect Estradiol assay.	Calibration verifier for multiple analytes.

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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

FEB 2 1999

Ms. Elizabeth Platt
Regulatory Affairs Supervisor
Bio-Rad Laboratories
Diagnostics Group
9500 Jeronimo Road
Irvine, California 92618-2017

Re: K984604
Trade Name: Architect™ Estradiol MasterCheck
Regulatory Class: I
Product Code: JJX
Dated: December 21, 1998
Received: December 28, 1998

Dear Ms. Platt:

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.

Under the Clinical Laboratory Improvement Amendments of 1988 (CLIA-88), this device may require a CLIA complexity categorization. To determine if it does, you should contact the Centers for Disease Control and Prevention (CDC) at (770) 488-7655.

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: K984604

Device Name: Architect Estradiol MasterCheck

Indications for Use:

Architect Estradiol MasterCheck is intended for use in the verification of sensitivity, calibration linearity, and reportable range of the Estradiol assay on the Abbott Architect *i* System.

Jean Cooper

(Division Sign-Off)

Division of Clinical Laboratory Devices

510(k) number K984604

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

(Concurrence of CDRH, Office of Device Evaluation)

Prescription Use ✓ OR Over-The Counter Use _____