



**Bio-Rad
Laboratories**

*Diagnostics Group
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510(k) Summary

Submitter

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Irvine, CA
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Contact Person

Elizabeth Platt

Date of Summary Preparation

December 02, 1998

Device (Trade & Common Name)

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



Description of the Device

Architect FSH MasterCheck Level 0 contains HEPES buffer with protein (bovine) stabilizers.

Architect FSH MasterCheck Levels 1, 2, 3 and 4 contain FSH (human) prepared in HEPES 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 FSH MasterCheck and the devices to which substantial equivalence is claimed.

	Architect FSH MasterCheck	Casco Standards Document Serum Multi-Analyte Verification Test Set
Intended Use	Verification of sensitivity, calibration linearity, and reportable range of the FSH assay on the Abbott Architect <i>i</i> System.	<i>In vitro</i> 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	HEPES buffer with protein (bovine) stabilizers	Human Serum
Storage	2-8°C	-10 to -20°C
Analytes	FSH	Multiple
Open Vial Claim	3 Days at 2-8°C.	30 Days at 2-8°C.
Differences	Calibration verifier for the Architect FSH assay	Calibration verifier for multiple analytes.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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

DEC 15 1998

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

Re: K984318
Trade Name: Architect FSH MasterCheck
Regulatory Class: I
Product Code: JJX
Dated: December 2, 1998
Received: December 3, 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.

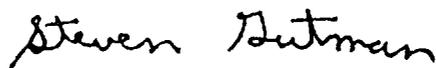
If your device is classified (see above) into either class II (Special Controls) or class III (Pre-market Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially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

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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: 15984318

Device Name: Architect FSH MasterCheck

Indications for Use:

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


(Division of) _____
Division of _____
510(k) Number 15984318

(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