FEB 2 1999

K984594

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, ECS Division
9500 Jeronimo Road
Irvine, CA 92618
(949)598-1285
Fax (949)598-1555

Contact Person

Elizabeth Platt

Date of Summary Preparation

December 22, 1998

Device (Trade & Common Name)

Lyphochek Maternal Serum Control

Classification Name

Class I, CFR 862.1660: Multi-Analyte Control
(Assayed and Unassayed)
75JJY

Devices to Which Substantial Equivalence is Claimed

Lyphochek Immunoassay Plus Control
Bio-Rad Laboratories, Irvine, California
K981532

Statement of Intended Use

Lyphochek Maternal Serum Control is intended for use as an assayed quality control to monitor the precision of laboratory testing procedures for the analytes listed in the package insert.

BIO-RAD **Bio-Rad Laboratories**

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

Description of the Device

Lyphochek Maternal Serum Control is prepared from human serum with added constituents of human origin, pure chemicals and preservatives. The control is provided in lyophilized form for increased stability.

Statement of How Technological Characteristics Compare to Substantial Equivalence Device

A table is provided below comparing the similarities between the Bio-Rad Lyphochek Maternal Serum Control and the device to which substantial equivalence is claimed.

	Bio-Rad Lyphochek Maternal Serum Control	Bio-Rad Lyphochek Immunoassay Plus Control
Intended Use	An assayed quality control serum to monitor the precision of laboratory testing procedures for the analytes listed in the package insert.	An assayed quality control serum to monitor the precision of laboratory testing procedures for the analytes listed in the package insert.
Form	Lyophilized	Lyophilized
Open Vial Claim	10 days when stored tightly capped at 2-8°C.	7 days when stored tightly capped at 2-8°C with the following exceptions: (1) C-Peptide, Folate and PSA are stable for 3 days after reconstitution. (2) ACTH, Calcitonin and Gastrin should be assayed immediately after reconstitution.
Matrix	Human serum	Human serum
Storage	2-8°C	2-8°C
Analytes	AFP (Alpha-Fetoprotein) Estriol, Free HCG-Beta Subunit	AFP (Alpha-Fetoprotein Estriol, Free HCG-Beta Subunit Plus other analytes.

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: K984594
Trade Name: Lyphochek Maternal Serum Control
Regulatory Class: I
Product Code: JJY
Dated: December 23, 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: K984594

Device Name: Lyphochek Maternal Serum Control

Indications for Use:

Lyphochek Maternal Serum Control is intended for use as an assayed quality control serum to monitor the precision of laboratory testing procedures for the analytes listed in the package insert.

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

Jean Cooper
Sign-Off)
of Clinical La
510(k) Number K984594

(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 _____