SEP -2 1999

K992172

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
June 25, 1999

Device (Trade & Common Name)
Lyphochek Tumor Marker Control

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

Devices to Which Substantial Equivalence is Claimed
Lyphochek Tumor Marker Control
Bio-Rad Laboratories
Irvine, California
K983807

Statement of Intended Use
Lyphochek Tumor Marker 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.

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Description of the Device

Lyphochek Tumor Marker Control is prepared from human serum with added constituents of human origin and pure chemicals. 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 Tumor Marker Control and the devices to which substantial equivalence is claimed.

	Bio-Rad Lyphochek Tumor Marker Control (New Device)	Bio-Rad Lyphochek Tumor Marker Control (Substantially Equivalent Device)
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
Matrix	Human serum	Human serum
Storage	2-8°C	2-8°C
Open Vial Claim	• 14 days when stored tightly capped at 2-8°C, with the following exceptions: ACTH, Free PSA, PSA and Calcitonin should be assayed immediately following reconstitution. • 30 days after reconstituting and freezing at -10°C to -20°C with the following exceptions: (1) PSA will be stable for 20 days when stored frozen at -10°C to -20°C and (2) ACTH and Calcitonin do not have frozen stability claims.	• 14 days when stored tightly capped at 2-8°C, with the following exceptions: ACTH, Free PSA, PSA and Calcitonin shoild be assayed immediately following reconstitution. • 30 days after reconstituting and freezing at -10°C to -20°C with the following exceptions: (1) PSA will be stable for 20 days when stored frozen at -10°C to -20°C and (2) ACTH and Calcitonin do not have frozen stability claims.
Differences	Same analytes as the substantially equivalent device and additional claims for the following : CA 50, CA 195, CA 549 and CASA.	Refer to attached substantially equivalent device product insert.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

SEP -2 1999

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

Re: K992172
Trade Name: Lyphochek Tumor Marker Control
Regulatory Class: I
Product Code: JJY
Dated: June 25, 1999
Received: June 28, 1999

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: K992172

Device Name: Lyphochek Tumor Marker Control

Indications for Use:

Lyphochek Tumor Marker 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.

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

(Concurrence of CDRH, Office of Device Evaluation)

(Division Sign-Off)
Division of Clinical Laboratory Devices
510(k) Number K992172

Prescription Use ✓ OR Over-The Counter Use _____