4/24/99

K990858

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
March 12, 1999

Device (Trade & Common Name)
Lyphochek Coagulation Control

Classification Name
Class II, 81GGN
CFR 864.5425: Plasma Coagulation Control

Devices to Which Substantial Equivalence is Claimed
Lyphochek Coagulation Control
Bio-Rad Laboratories
Irvine, California
K964963

Statement of Intended Use
Lyphochek Coagulation Control is intended for use as a quality control plasma to monitor the precision of citrated coagulation systems.

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Description of the Device

Lyphochek Coagulation Control is prepared from human plasma with added constituents of animal origin, purified biochemicals 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 Coagulation Control and the devices to which substantial equivalence is claimed.

	Bio-Rad Lyphochek Coagulation Control (New Device)	Bio-Rad Lyphochek Coagulation Control (Substantially Equivalent Device)
Intended Use	A quality control plasma to monitor the precision of citrated coagulation systems.	A quality control plasma to monitor the precision of citrated coagulation systems.
Form	Lyophilized	Lyophilized
Matrix	Human based control.	Human based control.
Storage	2-8°C	2-8°C
Open Vial Claim	24 hours days when stored tightly capped at 2-25°C.	24 hours days when stored tightly capped at 2-25°C.
Analytes	Prothrombin Time (PT), Activated Partial Thromboplastin Time (APTT), Fibrinogen, Antithrombin III (AT III), Thrombin Time (TT).	Prothrombin Time (PT), Activated Partial Thromboplastin Time (APTT), Fibrinogen.

Premarket Notification
Truthful and Accurate Statement

I certify that, in my capacity as Regulatory Affairs Supervisor of Bio-Rad Laboratories, ECS Division, I believe to the best of my knowledge, that all data and information submitted in the premarket notification are truthful and accurate and that no material fact has been omitted.

Elizabeth Platt
Regulatory Affairs Supervisor

3/12/95
Date

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

APR 21 1999

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

Re: K990858
Trade Name: Lyphochek Coagulation Control
Regulatory Class: II
Product Code: GGN
Dated: March 31, 1999
Received: April 2, 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: K990858

Device Name: Lyphochek Coagulation Control

Indications for Use:

Lyphochek Coagulation Control is intended for use as a quality control plasma to monitor the precision of citrated coagulation systems.

Peter E. Maheux

(Division Sign-Off)
Division of Clinical Laboratory Devices
510(k) Number K990858

(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 _____