Summary of Safety and Effectiveness
Lyphochek® Hemostasis Control

1.0 Submitter

Bio-Rad Laboratories
9500 Jeronimo Road,
Irvine, California 92618-2017
Telephone: (949) 598-1200
Fax: (949) 598-1555

Contact Person

Maria Zeballos
Regulatory Affairs Specialist
Telephone: (949) 598-1367

Date of Summary Preparation

March 15, 2002

2.0 Device Identification

Product Trade Name:	Lyphochek® Hemostasis Control
Common Name:	Control Plasma Normal Control Plasma Abnormal
Classifications:	Class II
Product Code:	GGC
Regulation Number:	21 CFR 864.5425

3.0 Device to Which Substantial Equivalence is Claimed

Coagulation S.A.C Assayed Control 1
Helena Laboratories
Beaumont, Texas

Docket Number: K941737

Coagulation S.A.C Assayed Control 2
Helena Laboratories
Beaumont, Texas

Docket Number: K941872

4.0 Description of Device

Lyphochek® Hemostasis Control is prepared from human plasma with added purified biochemicals and preservatives. The control is provided in lyophilized form for increased stability.

5.0 Statement of Intended Use

Lyphochek® Hemostasis Control is intended for use as a quality control plasma to monitor the precision of laboratory analytes listed in the package insert.

6.0 Comparison of the new device with the Predicate Device

Lyphochek® Hemostasis Control claims substantial equivalence to the Coagulation S.A.C Assayed Control 1 and 2 currently in commercial distribution.

Table 1. Similarities and Differences between new and predicate device.

Characteristics	Bio-Rad Lyphochek® Hemostasis Control (New Device)	Helena Laboratories Coagulation S.A.C.-1 Assayed Control 1 (Predicate Device - K941737)	Helena Laboratories Coagulation S.A.C.-2 Assayed Control 2 (Predicate Device - K941872).
Similarities			
Intended Use	Lyphochek® Hemostasis Control is intended for use as a quality control plasma to monitor the precision of laboratory testing procedures for analytes listed in the package insert.	S.A.C.-1 is assayed control plasma, which may be used in many facets of testing in the coagulation laboratory.	S.A.C.-2 is assayed abnormal control plasma, which may be used in many facets of testing in the coagulation laboratory.
Form	Lyophilized	Lyophilized	Lyophilized
Matrix	Human plasma based	Human plasma based	Human plasma based
Differences			
Storage (Unopened)	2-8°C Until expiration date	2–6°C Until expiration date	2–6°C Until expiration date
Reconstituted Vial Claim	8 hours at 2°C to 25°C with the following exception: Protein S will be stable for 8 hours at 2°C to 8°C.	4 hours 2-6°C	4 hours 2-6°C
Analytes	Contains: Prothrombin Time (PT), Activated Partial Thromboplastin Time (APTT), Fibrinogen, Antithrombin III (AT III) Thrombin Time (TT), Factor II, V, VII, VIII, IX, X, XI, XII, Protein S (Functional) and Protein C (Functional), Plasminogen Does not Contain: Alpha-Antiplasmin, von Willebrand Factor Antigen, Ristocetin cofactor	Contains: Prothrombin Time (PT), Activated Partial Thromboplastin Time (APTT), Fibrinogen, Antithrombin III (AT III), Factor II, V, VII, VIII, IX, X, XI, XII, Total and Free Protein S, Protein C, Plasminogen, von Willebrand Factor Antigen, Alpha-antiplasmin, Ristocetin cofactor Does not Contain: Thrombin Time (TT)	Contains: Prothrombin Time (PT), Activated Partial Thromboplastin Time (APTT), Fibrinogen, Antithrombin III (AT III), Factor II, V, VII, VIII, IX, X, XI, XII, Total and Free Protein S, Protein C, Plasminogen, Ristocetin cofactor, Alpha-antiplasmin, Monoclonal Free Protein S, von Willebrand Factor Antigen Does not Contain: Thrombin Time (TT)

7.0 Summary of Performance Data

Stability studies have been performed to determine the reconstituted stability and shelf life for the Lyphochek® Hemostasis Control. Product claims are as follows:

7.1 Reconstituted Stability: Once the control material is reconstituted, all analytes will be stable for 8 hours at 2°C to 25°C with the exception of Protein S which will be stable for 8 hours at 2°C to 8°C.

7.2 Shelf Life: Three years when stored at 2 to 8 °C.

Real time studies will be ongoing to support the shelf life of this product.
All supporting data is retained on file at Bio-Rad Laboratories.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

APR 1 5 2002

Ms. Maria Zeballos
Regulatory Affairs Specialist
Bio-Rad Laboratories
9500 Jeronimo Road
Irvine, California 92618-2017

Re: k020878
Trade/Device Name: Lyphochek® Hemostasis Control
Regulation Number: 21 CFR § 864.5425
Regulation Name: Control Plasma Abnormal
Regulatory Class: II
Product Code: GGC
Dated: March 15, 2002
Received: March 18, 2002

Dear Ms. Zeballos:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and 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) that do not require approval of a premarket approval application (PMA). 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 (PMA), 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 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

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" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers International and Consumer 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 (if known): K020878

Device Name: **Lyphochek® Hemostasis Control**

Indications for Use:

Lyphochek® Hemostasis Control is intended for use as a quality control plasma 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 (ODE)

Prescription use ✓ or Over-the Counter use_____

Josephine Bautista

(Division Sign-Off)
Division of Clinical Laboratory Devices
510(k) Number K020878