NOV - 5 2004

Bio-Rad Laboratories
Liquichek Reticulocyte Control (A)
Summary of Safety and Effectiveness

1.0 **Submitter**

Bio-Rad Laboratories
9500 Jeronimo Road,
Irvine, California 92618-2017
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Contact Person

Maria Zeballos
Regulatory Affairs Specialist
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Date of Summary Preparation

October 11, 2004

2.0 **Device Identification**

Product Name:	Liquichek Reticulocyte Control (A)
Common Name:	Hematology and Pathology Devices Hematology quality control mixture)
Classifications:	Class II
Product Code:	JPK
Regulation Number:	21 CFR 864.8625

3.0 **Device to Which Substantial Equivalence is Claimed**

Liquichek Reticulocyte Control
Bio-Rad Laboratories (formerly known as Hematronix, Inc.)
Benicia, California 94510

510 (k) Number: K993496

4.0 **Description of Device**

This is a liquid product composed of stabilized human red blood cells suspended in a buffered fluid with added constituents of animal origin and preservatives.

5.0 **Intended Use**

Liquichek Reticulocyte Control (A) is an assayed whole blood control for evaluating precision of automated methods of reticulocyte counting.

6.0 Comparison of the new device with the Predicate Device

Liquichek Reticulocyte Control (A) claims substantial equivalence to the Liquichek Reticulocyte Control currently in commercial distribution (K993496). Both of these are liquid, whole blood based controls for evaluating precision of reticulocyte counting.

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

Characteristics	Bio-Rad Laboratories Liquichek™ Reticulocyte Control (A) (New Device)	Bio-Rad Laboratories (formerly known as Hematronix, Inc.) Liquichek Reticulocyte Control (Predicate Device K993496)
Similarities		
Intended Use	Liquichek Reticulocyte Control (A) is an assayed whole blood control for evaluating precision of automated methods of reticulocyte counting.	Liquichek Reticulocyte Control is a whole blood reference control material designed to verify the precision of COULTER instruments equipped with reticulocyte measuring capabilities using VCS technology, and New Methylene Blue Stain.
Form	Liquid	Liquid
Analytes	Reticulocyte	Reticulocyte
Matrix	Human Whole Blood based	Human Whole Blood based
Preservatives	Contains preservatives	Contains preservatives
Storage (Unopened)	2°C to 8°C Until expiration date	2°C to 8°C Until expiration date
Differences		
Open Vial Claim	21 days at 2°C to 8 °C	31 days at 2 to 8°C

7.0 Statement of Supporting Data

Stability studies have been performed to determine the open vial stability and shelf life for the Lyphochek Elevated Immunosuppressant Control. Product claims are as follows:

- Open vial Stability: 21 days at 2 to 8°C.
- Shelf Life: 110 days at 2 to 8 °C

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

NOV - 5 2004

Ms. Elizabeth Platt
Regulatory Affairs/Quality Assurance Manager
Bio-Rad Laboratories, QSD
9500 Jeronimo Road
Irvine, California 92618-2017

Re: k042836
Trade/Device Name: Liquichek Reticulocyte Control (A)
Regulation Number: 21 CFR § 864.8625
Regulation Name: Hematology Quality Control Mixture
Regulatory Class: II
Product Code: JPK
Dated: October 11, 2004
Received: October 14, 2004

Dear Ms. Platt:

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 Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. 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 Parts 801 and 809); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820). This letter will allow you to begin marketing your device as described in your Section 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 information about the application of labeling requirements to your device, or questions on the promotion and advertising of your device, please contact the Office of In Vitro Diagnostic Device Evaluation and Safety at (301) 594-3084. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act 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,

Robert L. Becker, Jr., M.D., Ph.D.
Director
Division of Immunology and Hematology Devices
Office of In Vitro Diagnostic Device Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K042836

Device Name: **Liquichek Hematology Control (A)**

Indications For Use: **Liquichek Reticulocyte Control (A) is an assayed whole blood control for evaluating precision of automated methods of reticulocyte counting.**

Prescription Use __X__ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

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

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

Division Sign-Off

Office of In Vitro Diagnostic Device
Evaluation and Safety

510(k) K042836