K121143

MAY 18 2012

Summary of Safety and Effectiveness
Liquichek Whole Blood Immunosuppressant control

1.0 Submitter

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Contact Person

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Date of Summary Preparation

May 17, 2012

2.0 Device Identification

Product Trade Name:	Liquichek Whole Blood Immunosuppressant Control
Common Name:	Drug Mixture Control Materials
Classifications:	Class I, Reserved
Product Code:	DIF
Regulation Number:	21 CFR 862.3280

3.0 Device to Which Substantial Equivalence is Claimed

Lyphochek Whole Blood Immunosuppressant Control
Bio-Rad Laboratories
Irvine, California

510 (k) Number: K072721

4.0 Description of Device

This product is prepared from human whole blood with added preservatives and stabilizers. The control is provided in liquid form for convenience.

Mean values for control levels 1-4 of each analyte, derived from replicate analyses, are listed in the package insert. Each laboratory should establish its own means and acceptable ranges based on their own test system and tolerance limits.

5.0 Intended Use

Liquichek Whole Blood Immunosuppressant Control is intended for use as an assayed quality control material to monitor the precision of laboratory testing procedures for the analytes listed in the package insert.

6.0 Comparison of the new device with the Predicate Device

Table 1: Similarities and Differences between new and predicate device

Characteristics	Liquichek Whole Blood Immunosuppressant Control *(New Device)*	Lyphochek Whole Blood Immunosuppressant Control *(Predicate Device, K072721)*
Similarities		
Intended Use	Liquichek Whole Blood Immunosuppressant Control is intended for use as an assayed quality control material to monitor the precision of laboratory testing procedures for the analytes listed in the package insert.	Lyphochek Whole Blood Immunosuppressant Controls are intended for use as an assayed quality control material to monitor the precision of laboratory testing procedures for the analytes listed in the package insert.
Matrix	Whole Blood	Whole Blood
Open Vial Stability	Tacrolimus : 10 days at 2 to 8 °C All other analytes: 14 days at 2 to 8 °C	14 days at 2 to 8 °C (reconstituted)
Shelf Life Storage & Stability	Until expiration date at -20°C to -70°C	Until expiration date at -20°C to -70°C
Differences		
Form	Liquid	Lyophilized
Reconstituted & Frozen Stability	No claim	30 days when stored at -20°C to -70°C
Analytes	**Contains:** Cyclosporine Tacrolimus Sirolimus Everolimus	**Contains:** Cyclosporine Tacrolimus Sirolimus **Does not contain:** Everolimus

7.0 Statement of Supporting Data

Stability studies have been performed for Liquichek Whole Blood Immunosuppressant control to determine the open vial stability and shelf life claims. Product claims are as follows:

7.1 **Open Vial Stability:** Tacrolimus will be stable for 10 days at 2 to 8 °C.
All other analytes will be stable for 14 days.

7.2 **Shelf Life Stability**: 40 months at -20°C to -70° C

8.0 Conclusion

Liquichek Whole Blood Immunosuppressant Control is intended to be used for the same purposes as the predicate device. It has the whole blood matrix and performs similarly as the predicate device.

All supporting data is retained on file at Bio-Rad Laboratories.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration

10903 New Hampshire Avenue
Silver Spring, MD 20993

Bio-Rad Laboratories
c/o Suzanne Parsons
Regulatory Affairs/QA/QC Manager
9500 Jeronimo Road
Irvine, CA 92618-2017, USA

MAY 18 2012

Re: k121143
Trade Name: Liquichek Whole Blood Immunosuppressant Control
Regulation Number: 21 CFR §862.3280
Regulation Name: Quality Control Material (Assayed and Unassayed)
Regulatory Class: Class I, reserved
Product Codes: DIF
Dated: April 12, 2012
Received: April 16, 2012

Dear Ms. Parsons:

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); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820).

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of In Vitro Diagnostic Device Evaluation and Safety at (301) 796-5450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (301) 796-5760. For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance...

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) 796-5680 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm

Sincerely yours,

Courtney H. Lias, Ph.D.
Director
Division of Chemistry and Toxicology Devices
Office of *In Vitro* Diagnostic Device
Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

Indications for Use Form

510(k) Number (if known): K121143

Device Name: **Liquichek Whole Blood Immunosuppressant Control**

Indications for Use:

Liquichek Whole Blood Immunosuppressant Control is intended for use as an assayed quality control material to monitor the precision of laboratory testing procedures for the analytes listed in the package insert.

The following analytes are listed in the package insert:

- Sirolimus
- Tacrolimus
- Cyclosporine
- Everolimus

Prescription Use X (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (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) K121143