JUL - 6 2004

K041561

Summary of Safety and Effectiveness

Liquichek Whole Blood Volatiles Control

1.0 **Submitter**

Bio-Rad Laboratories
9500 Jeronimo Road,
Irvine, California 92618-2017
Telephone: (949) 598-1200
Fax: (949) 598-1557

Contact Person

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

Date of Summary Preparation

June 08, 2004

2.0 **Device Identification**

Product Trade Name:	Liquichek Whole Blood Volatiles Control
Common Name:	Clinical Toxicology Control Material
Classifications:	Class I
Product Code:	DIF
Regulation Number:	21 CFR 862.3280

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

Whole Blood Tox Control
Bio-Rad Laboratories
Irvine, California

510 (k) Number: K821975A

4.0 **Description of Device**

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

5.0 **Intended Use**

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

6.0 Preservatives:

The Liquichek Whole Blood Volatiles Control does not contain sodium azide as a preservative. It contains a broad-spectrum anti-microbial cocktail as a preservative where the concentration of any one ingredient is less than 0.1%. At this low level, these ingredients are not expected to cause a health hazard to the user. And thus, domestic and international regulations do not require this type of information on the vial or box label.

7.0 Comparison of the new device with the Predicate Device

Liquichek Whole Blood Volatiles Control claims substantial equivalence to Whole Blood Tox Control currently in commercial distribution (K821975A).

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

Characteristics	Bio-Rad Laboratories Liquichek Whole Blood Volatiles Control (New Device)	Bio-Rad Laboratories Whole Blood Tox Control (Predicate Device K821975A)
Similarities		
Intended Use	Liquichek Whole Blood Volatiles Control is intended for use as a quality control material to monitor the precision of laboratory testing procedures for the analytes listed in the package insert.	Use Whole Blood Tox quality control material, assayed, to monitor the precision of whole blood toxicology test procedures.
Form	Liquid	Liquid
Matrix	Whole Blood	Whole Blood
Preservatives	Contains preservatives	Contains preservatives
Storage (Unopened)	2°C to 8°C Until expiration date	2°C to 8°C Until expiration date
Open Vial	5 days at 2°C to 8°C	5 days at 2°C to 8°C
Differences		
Analytes	Contains the following analytes: • Acetone • Ethanol • Isopropanol • Lead • Methanol Does not contain: • Phenylalanine	Contains the following analytes: • Ethanol • Isopropanol • Lead • Methanol • Phenylalanine Does not contain: • Acetone

8.0 Statement of Supporting Data

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

8.1 Open Vial Stability: 5 days at 2 to 8°C.

8.2 Shelf Life: 2 years 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

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

JUL - 6 2004

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

Re: k041561
Trade/Device Name: Liquichek Whole Blood Volatiles Control
Regulation Number: 21 CFR 862.3280
Regulation Name: Clinical toxicology control material
Regulatory Class: Class I
Product Code: DIF
Dated: June 8, 2004
Received: June10, 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,

Jean M. Cooper MS, DVM.

Jean M. Cooper, MS, D.V.M.
Director
Division of Chemistry and Toxicology
Office of *In Vitro* Diagnostic Device
Evaluation and Safety
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K041561

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

Indications For Use: **Liquichek Whole Blood Volatiles Control is intended for use as a quality control material to monitor the precision of laboratory testing procedures for the analytes listed in the package insert.**

Prescription Use ✓ 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) K041561