K 022991

Summary of Safety and Effectiveness
Liquichek™ Immunology Control

1.0 Submitter

SEP 17 2002

Bio-Rad Laboratories
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Contact Person

Maria Zeballos
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Date of Summary Preparation

September 2, 2002

2.0 Device Identification

Product Trade Name:	Liquichek™ Immunology Control
Common Name:	Multi-Analyte Controls, (Assayed and unassayed)
Classifications:	Class I
Product Code:	75JJY
Regulation Number:	CFR 862.1660

3.0 Device to Which Substantial Equivalence is Claimed

Liquichek™ Immunology Control
Bio-Rad Laboratories
Irvine, California

Docket Number: K011494

4.0 Description of Device

Liquichek™ Immunology Control is prepared from human serum with added serum proteins, constituents of animal origin, preservatives and stabilizers. The control is provided in liquid form for convenience.

5.0 Statement of Intended Use

Liquichek™ Immunology Control is intended for use as an assayed quality control serum to monitor the precision of laboratory testing procedures for analytes listed in this package insert.

6.0 Comparison of the new device with the Predicate Device

The new Liquichek™ Immunology Control claims substantial equivalence to the Liquichek™ Immunology Control currently in commercial distribution (K011494). The new Liquichek™ Immunology Control contains ADNase B, C1-Inhibitor, Cystatin-C, IgG subclasses, Lp (a) and the current product does not.

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

Characteristics	Bio Rad Liquichek™ Immunology Control (New Device)	Bio Rad Liquichek™ Immunology Control (Predicate Device)
Similarities		
Intended Use	Liquichek™ Immunology Control is intended for use as an assayed quality control serum to monitor the precision of laboratory testing procedures for analytes listed in this package insert.	Liquichek™ Immunology Control is intended for use as an assayed quality control serum to monitor the precision of laboratory testing procedures for analytes listed in this package insert.
Form	Liquid	Liquid
Matrix	Human serum based	Human serum based
Storage (Unopened Frozen)	-10 °C to –20°C until expiration date	-10 °C to –20°C until expiration date
Storage (Unopened Thawed)	90 days at 2-8° C	90 days at 2-8° C
Open Vial Claim	30 days at 2-8° C with the following exception: Rheumatoid Factor is stable for 21 days at 2 to 8°C	30 days at 2-8° C with the following exception: Rheumatoid Factor is stable for 21 days at 2 to 8°C
Differences		
	Same analytes as the predicate device with the additional claims for ADNase B, C1-Inhibitor, Cystatin-C, IgG subclasses, and Lp (a).	ADNase B, C1-Inhibitor, Cystatin-C, IgG subclasses, and Lp (a) are not included.

7.0 Summary of Performance Data

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

7.1 Open vial: Once the product is thawed and opened, all analytes will be stable for 30 days when stored tightly capped at 2 to 8°C with the exception of Rheumatoid Factor, which will be stable for 21 days.

7.2 Closed Vial: Once thawed and stored unopened at 2 to 8°C, all analytes will be stable for 90 days.

7.3 Shelf Life: Two years when stored at –10 to –20 °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

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

SEP 17 2002

Re: k022991
Trade/Device Name: Liquichek™ Immunology Control
Regulation Number: 21 CFR § 862.1660
Regulation Name: Quality Control Material (Assayed and Unassayed)
Regulatory Class: I
Product Code: JJY
Dated: September 6, 2002
Received: September 9, 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): K022991

Device Name: **Liquichek™ Immunology Control**

Indications for Use:

An assayed quality control serum to monitor the precision of laboratory testing procedures for analytes listed in the package insert.

(PLEASE DO NOT WRITE BELOW THE LINE-CONINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription use ✓ or Over-the Counter use _____

Deborah M. Moore

(Division Sign-Off)
Division of Clinical Laboratory Devices
510(k) Number K022991