K042446

NOV - 2 2004

Summary of Safety and Effectiveness
qUAntify Control and qUAntify Plus Control

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

September 3, 2004

2.0 **Device Identification**

Product Trade Name:	qUAntify Control and qUAntify Plus Control
Common Name:	Urinalysis controls (Assayed and Unassayed)
Classifications:	Class I
Product Code:	JJW
Regulation Number:	21 CFR 862.1660

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

Liquichek™ Urinalysis Control
Bio-Rad Laboratories
Irvine, California

510 (k) Number: K031231

4.0 **Description of Device**

These products are a liquid matrix solution prepared with human erythrocytes and [leukocytes in qUAntify Plus only], constituents of animal origin, chemicals, and preservatives.

5.0 **Intended Use**

qUAntify Control and qUAntify Plus Control are intended for use as an assayed quality control to monitor the precision of urinalysis test procedures listed in their respective package inserts.

6.0 **Preservatives:**

qUAntify Control and qUAntify Plus Control contain preservatives in a concentration of less than 0.1%. At this low level, the 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

qUAntify Control and qUAntify Plus Control claim substantial equivalence to the Liquichek Urinalysis Control currently in commercial distribution (K031231).

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

Characteristics	Bio-Rad Laboratories qUAntify Control and qUAntify Plus Control (New Device)		Bio-Rad Laboratories Liquichek™ Urinalysis Control (Predicate Device -K031231)
Similarities			
Intended Use	[qUAntify Control] [qUAntify Plus Control] is intended for use as an assayed quality control to monitor the precision of urinalysis test procedures for the analytes listed in this package insert.		Liquichek Urinalysis Control is intended for use as an assayed quality control urine to monitor the precision of urinalysis test procedures for the analytes listed in the package insert.
Form	Liquid		Liquid
Storage Stability	2°C to 8°C Until expiration date		2°C to 8°C Until expiration date
Differences			
Matrix	Liquid matrix solution		Human Urine
Open Vial	31 days at 2 to 8°C or room temperature (18 to 25°C)		30 days at 2 to 8° C or 7 days at room temperature (18-25° C)
Analytes	qUAntify Control contains the following analytes:	qUAntify Plus Control contains the following analytes:	Contains the following analytes:
	Albumin Albumin-to-Creatinine Ratio Ascorbic Acid Bilirubin Blood Creatinine Glucose hCG Hemoglobin Ketones Leukocytes Nitrite Microalbumin Protein-to-Creatinine Ratio Protein, Total pH Urobilinogen Specific Gravity	Albumin Albumin-to-Creatinine Ratio Ascorbic Acid Bilirubin Blood Crystals Casts Creatinine Glucose hCG Hemoglobin Ketones Leukocytes Microalbumin Nitrite Protein-to-Creatinine Ratio Protein, Total pH Urobilinogen Red Blood Cells (RBC) Specific Gravity White Blood Cells (WBC)	Bilirubin Blood Creatinine Glucose hCG (also described as Pregnancy) Ketones Microalbumin Leukocytes Nitrite Protein-to-Creatinine Ratio Protein, Total pH Urobilinogen Red Blood Cells (RBC) White Blood Cells (WBC) Crystals Casts Osmolality Specific Gravity
	Does not contain:	Does not contain:	Does not contain:
	Osmolality Red Blood Cells (RBC) White Blood Cells (WBC) Crystals Casts	Osmolality	Albumin Albumin-to-Creatinine Ratio Ascorbic Acid Hemoglobin

8.0 Statement of Supporting Data

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

- Open vial Stability: 31 days at 2 to 8°C or room temperature (18 to 25°C) .
- Shelf Life: Two years 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 - 2 2004

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

Re: k042446
Trade/Device Name: qUAntify® Control
qUAntify® Plus Control
Regulation Number: 21 CFR 862.1660
Regulation Name: Quality control material (assayed and unassyed)
Regulatory Class: Class I
Product Code: JJW
Dated: September 3, 2004
Received: September 9, 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

K042446

Indications for Use

510(k) Number (if known): K042446

Device Name: **qUAntify® Control**

Indications For Use: qUAntify® Control is intended for use as an assayed quality control to monitor the precision of urinalysis test procedures for the analytes listed in the package insert.

Device Name: **qUAntify® Plus Control**

Indications For Use: qUAntify® Plus Control is intended for use as an assayed quality control to monitor the precision of urinalysis test procedures for the analytes listed in the package insert.

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)

Carol C Benson
Division Sign-Off

Office of In Vitro Diagnostic
Device Evaluation and Safety

510(k) K042446