K033387

DEC - 2 2003

Summary of Safety and Effectiveness
Quest Diagnostics Serum Chemistry Control

1.0 Submitter

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

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Date of Summary Preparation

October 15, 2003

2.0 Device Identification

Product Trade Name:	Quest Diagnostics Serum Chemistry Control
Common Name:	Multi-Analyte Controls, (Assayed and Unassayed)
Classifications:	Class I
Product Code:	JJY
Regulation Number:	CFR 862.1660

3.0 Device to Which Substantial Equivalence is Claimed

Bio-Rad Laboratories
Liquid Assayed Multiqual Control
Irvine, California
Docket Number: K011867

4.0 Description of Device

Quest Diagnostics Serum Chemistry Control is prepared from human serum to which purified biochemical materials (tissue extracts of human and animal origin), chemicals, preservatives, and stabilizers have been added.

5.0 Statement of Intended Use

Quest Diagnostics Serum Chemistry Control is intended for use as a quality control serum to monitor the precision of an individual laboratory's automated and manual-testing procedures.

6.0 Comparison of the new device with the Predicate Device

Quest Diagnostics Serum Chemistry Control claims substantial equivalence to the Liquid Assayed Multiqual Control currently in commercial distribution (K011867).

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

Characteristics	Quest Diagnostics Serum Chemistry Control (New Device)	Bio-Rad Liquid Assayed Multiqual Control (Predicate Device K011867)
Similarities		
Intended Use	Quest Diagnostics Serum Chemistry Control is intended for use as a quality control serum to monitor the precision of an individual laboratory's automated and manual-testing procedures.	Liquid Assayed Multiqual 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
Other ingredients	Stabilizers and preservatives	Stabilizers and preservatives
Differences		
Storage (Unopened Frozen)	-10 °C to –20°C Until expiration date	–20°C or colder Until expiration date
Open Vial Claim	10 days at 2-8° C	14 days 2-8° C
Storage (Unopened Thawed)	No claim	30 days at 2-8° C
Analytes	Contains the following analytes that are equivalent to the predicate device: ALT; Albumin; Alkaline Phosphatase; Amylase; AST; Direct Bilirubin; Total Bilirubin; Blood Urea Nitrogen; Calcium; Chloride; Cholesterol; Cholesterol, HDL; CO2; Creatine Kinase (CK); Creatinine; Gamma-Glutamyltransferase; Glucose; Iron; Lactate Dehydrogenase (LDH); Lipase; Magnesium; Phosphorous; Potassium; Sodium; T3 Uptake; T4 Total; Total Protein; Triglycerides; Iron-Binding Capacity, Unsaturated (UIBC); Uric Acid.	Contains the following additional analytes not claimed in the new product: Acetaminophen; Acid Phosphatase; Amikacin; Amylase, Pancreatic; Bilirubin, Neonatal; Calcium, ionized; Carbamazepine; Cholesterol, HDL; Cholesterol, LDL; CK-MB Isoenzyme; Cortisol; Digoxin; Ethyl Alcohol; Gentamicin; α-1-Antitripsin; HBDH; ApoA; ApoB; C3 Complement; C4 Complement; Ceruloplasmin; Cholinesterase; Copper; Ferritin; Globulin; Lithium; Osmolality; Phenobarbital; Phenytoin; Phospholipids; PAP; Salicylate; T_3 Free; T_3 Uptake/T Uptake; T_4 Free; Theophylline; TSH; Tobramycin; Valproic Acid; Haptoglobin; IgA ; IgG; IgM; TIBC; LAP Arylamidase; Prealbumin; Protein Electrophoresis; Transferrin; Vitamin B_{12}; Zinc.

7.0 STATEMENT OF SUPPORTING DATA

Stability studies have been performed to determine the open vial stability and shelf life for the Quest Diagnostics Serum Chemistry Control. Product claims are as follows:

7.1 Open vial: 10 days when stored tightly capped at 2-8°C.

7.2 Shelf Life: Two years when stored at –10 to –20 °C.

7.3 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

DEC - 2 2003

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

Re: k033387
Trade/Device Name: Quest Diagnostics Serum Chemistry Control
Regulation Number: 21 CFR 862.1660
Regulation Name: Quality control material (assayed and unassayed)
Regulatory Class: Class I
Product Code: JJY
Dated: October 15, 2003
Received: October 24, 2003

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,

Steven Gutman

Steven I. Gutman, M.D., M.B.A.
Director
Office of *In Vitro* Diagnostic Device
Evaluation and Safety
Center for Devices and
Radiological Health

Enclosure

510 (k) Number (if known): K033387

Device Name: **Quest Diagnostics Serum Chemistry Control**

Indications for Use:

For use as a quality control serum to monitor the precision of an individual laboratory's automated and manual-testing procedures.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription use X or Over-the Counter use _____

Carol C Benson for Jean Cooper, DVM

Division Sign-Off

Office of In Vitro Diagnostic Device Evaluation and Safety

510(k) K033387