K042815

Summary of Safety and Effectiveness
Quest Diagnostics Tumor Marker Control

NOV - 5 2004

1.0 Submitter

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Date of Summary Preparation

November 2, 2004

2.0 Device Identification

Product Trade Name:	Quest Diagnostics Tumor Marker Control
Common Name:	Multi-analyte Controls, (Assayed and unassayed)
Classifications:	Class I
Product Code:	JJY
Regulation Number:	21 CFR 864.1660

3.0 Device to Which Substantial Equivalence is Claimed

Lyphochek Tumor Marker Control
Bio-Rad Laboratories
Irvine, California

510 (k) Number: K011579

4.0 Description of Device

This product is prepared from human serum with added chemicals, constituents of human and animal origin. This product is provided in lyophilized form for added stability.

5.0 Intended Use

Quest Diagnostics Tumor Marker Control is intended for use as a quality control serum 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

Quest Diagnostics Tumor Marker Control claims substantial equivalence to the Lyphochek Tumor Marker Control currently in commercial distribution (K011579).

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

Characteristics	Quest Diagnostics Tumor Marker Control (New Device)	Bio-Rad Laboratories Lyphochek Tumor Marker Control (Predicate Device K011579)
Similarities		
Intended Use	Quest Diagnostics Tumor Marker Control is intended for use as a quality control serum to monitor the precision of laboratory testing procedures for the analytes listed in the package insert.	Lyphochek Tumor Marker Control is intended for use as an assayed quality control serum to monitor the precision of laboratory testing procedures for the analytes listed in the package insert.
Form	Lyophilized	Lyophilized
Matrix	Human Serum	Human Serum
Preservatives	Does not Contains preservatives	Does not Contains preservatives
Storage (Unopened)	2°C to 8°C Until expiration date	2°C to 8°C Until expiration date
Reconstituted Vial Claim	14 days at 2°C to 8°C	All analytes will be stable for 14 days at 2 to 8°C, with the following exceptions: Ferritin and CA 27-29 will be stable for 6 days. ACTH, Free PSA, PSA, and Calcitonin should be assayed immediately following reconstitution
After Reconstituting and Freezing	All analytes 30 days at -10 to -20°C	All analytes 30 days at -10 to -20°C
Differences		
Analytes	Contains the following analytes: • CA 15-3 • CA 125 • CA 19-9 • CA 27.29 [Footnote #2 listed in chart] Does not contain the following analytes: • ACTH • AFP (Alpha Fetoprotein) • Aldosterone • Beta-2-Microglobulin • CA 50 • CA 72-4 • Calcitonin • CASA • CEA (Carcinoembryonic Antigen) • CYFRA 21-1 • Ferritin • hCG (Human Chorionic Gonadotropin) • hCG – Beta Subunit • NSE (Neuron Specific Enolase) • PAP (Prostatic Acid Phosphatase) • Prolactin • PSA (Prostate Specific Antigen)	Contains the following analytes: • ACTH • AFP (Alpha Fetoprotein) • Aldosterone • Beta-2-Microglobulin • CA 15-3 • CA 19-9 • CA 27-29 • CA 50 • CA 72-4 • CA 125 • Calcitonin • CASA • CEA (Carcinoembryonic Antigen) • CYFRA 21-1 • Ferritin • hCG (Human Chorionic Gonadotropin) • hCG – Beta Subunit • NSE (Neuron Specific Enolase) • PAP (Prostatic Acid Phosphatase) • Prolactin • PSA (Prostate Specific Antigen)

7.0 Statement of Supporting Data

Stability studies have been performed to determine the open vial stability and shelf life for the Quest Diagnostics Tumor Marker Control. Product claims and a summary of the protocols used to establish claims are as follows:

- Open vial Stability: 14 days at 2 to 8°C.
- After reconstituting and freezing: 30 days at –10 to -20°C.
- Shelf Life: Three years and three months when stored at 2 to 8 °C

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

NOV - 5 2004

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

Re: k042815
Trade/Device Name: Quest Diagnostics Tumor Marker Control Levels 1, 2 and 3
Regulation Number: 21 CFR 862.1660
Regulation Name: Quality control material (assayed and unassayed)
Regulatory Class: Class I
Product Code: JJY
Dated: October 5, 2004
Received: October 12, 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,

Robert L. Becker, Jr., M.D., Ph.D.
Director
Division of Immunology and Hematology Devices
Office of In Vitro Diagnostic Device Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K042815

Device Name: Quest Diagnostics Tumor Marker Control

Indications For Use: Quest Diagnostics Tumor Marker Control is intended for use as a quality control serum to monitor the precision of laboratory testing 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)

Division Sign-Off

Office of In Vitro Diagnostic Device
Evaluation and Safety

510(k) K042815