DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

BIO-RAD LABORATORIES
SUZANNE PARSONS
REGULATORY AFFAIRS MANAGER
9500 JERONIMO ROAD
IRVINE CA 92618-2017

May 11, 2017

Re: K163015
Trade/Device Name: Liquichek Tumor Marker Control-level 1; Liquichek Tumor Marker Control-level 2; Liquichek Tumor Marker Control-level 3; Liquichek Tumor Marker Control- Trilevel Minipak
Regulation Number: 21 CFR 862.1660
Regulation Name: Quality control material (assayed and unassayed)
Regulatory Class: I, Reserved
Product Code: JJY
Dated: October 26, 2016
Received: October 28, 2016

Dear Ms. Parsons:

This letter corrects our substantially equivalent letter of January 10, 2017.

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. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to 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 Parts 801 and 809); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); 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.

If you desire specific advice for your device on our labeling regulations (21 CFR Parts 801 and 809), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Kelly Oliner -S

For
Leonthena Carrington, MBA, MS, MT(ASCP)
Director
Division of Immunology and Hematology Devices
Office of In Vitro Diagnostics
and Radiological Health
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K163015

Device Name
Liquichek Tumor Marker Control

Indications for Use *(Describe)*
Liquichek Tumor Marker Control is intended for use as an assayed quality control serum to moni tor the precision of laboratory testing procedures for the analytes listed in this package insert.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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510(k) Summary

Liquichek Tumor Marker Control

1.0 Submitter

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Fax: (949) 598-1557

Contact Person

Suzanne Parsons
RA/QA Supervisor
Telephone: (949) 598-1467

Date of Summary Preparation

January 3rd 2017

2.0 Device Identification

Product Trade Name:	Liquichek Tumor Marker Control
Common Name:	Multi-Analyte Controls, All Kinds (Assayed)
Classifications:	Class I, Reserved
Product Code:	JJY
Regulation Number:	21 CFR 862.1660

3.0 Device to Which Substantial Equivalence is Claimed

Liquichek Tumor Marker Control
Bio-Rad Laboratories
Predicate 510(k) Number: K071675

4.0 Description of Device

Liquichek Tumor Marker Control is prepared from human source material with added constituents of human and animal origin, chemicals, stabilizers and preservatives. The control is provided in liquid form for convenience.

The human source material used to manufacture this control was tested by FDA accepted methods and found non-reactive for Hepatitis B Surface Antigen (HBsAg), antibody to Hepatitis C (HCV) and antibody to HIV-1/HIV-2.

5.0 Value Assignment

The mean values and corresponding ±3SD ranges in the Assignment of Values Data Charts were derived from replicate analyses and are specific for this lot of product. Data from Unity™ Interlaboratory Program are included in the determination of some ranges.

The tests listed were performed by the manufacturer and/or independent laboratories using manufacturer supported reagents and a representative sampling of this lot of product. It is recommended that each laboratory establish its own acceptable ranges and use those provided only as guides. Laboratory established ranges may vary from those listed during the life of this control. Variations over time and between laboratories may be caused by differences in laboratory technique, instrumentation and reagents, or by manufacturer test method modifications.

6.0 Intended Use

Liquichek 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 this package insert.

7.0 Comparison of the new device with the Predicate Device

Liquichek Tumor Marker Control claims substantial equivalence to Liquichek Tumor Marker Control (*K071675*). Table 1 (below) contains comparison information of similarities and differences between the new and predicate device to which substantial equivalence is claimed.

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

Characteristics	Liquichek Tumor Marker Control *(New Device)*	Liquichek Tumor Marker Control (*Predicate Device,* K071675*)*
Similarities		
Intended Use	Liquichek 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 this package insert.	Liquichek 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 this package insert.
Matrix	Human source material and constituents of animal origin	Human source material and constituents of animal origin
Form	Liquid	Liquid
Storage unopened (Shelf life)	-20°C to -70°C until expiration date	-20°C to -70°C until expiration date
Thawed Unopened Stability	All analytes: 60 days at 2 to 8°C *Except* IGF-I, PAP: 35 days at 2 to 8°C Free PSA: 30 days at 2 to 8°C CA 125: 14 days at 2 to 8°C	All analytes: 60 days at 2 to 8°C *Except* IGF-I, PAP: 35 days at 2 to 8°C Free PSA: 30 days at 2 to 8°C CA 125: 14 days at 2 to 8°C
Thawed Opened Stability	All analytes: 30 days at 2 to 8°C *Except* IGF-1: 15 days at 2 to 8°C CA 125: 10 days at 2 to 8°C	All analytes: 30 days at 2 to 8°C *Except* IGF-1: 15 days at 2 to 8°C CA 125: 10 days at 2 to 8°C
Fill Volume	Level 1, 2 and 3 – 6 x 2 mL Trilevel MiniPak - 3 x 2 mL	Level 1, 2 and 3 – 6 x 2 mL Trilevel MiniPak - 3 x 2 mL
Differences		
Frozen aliquot	30 days at -20 to -70 ºC	No Claim

Analytes	Contains:	Contains:
	• Alpha Fetoprotein (AFP) • Beta-2-Microglobulin (B2-M) • CA 15-3 • CA 19-9 • CA 27.29 • CA 125 • Carcinoembryonic Antigen (CEA) • Ferritin • Her-2/neu • Human Chorionic Gonadotropin (hCG)/(β-hCG, Total hCG, Intact hCG) • Human Epididymis Protein 4 (HE4) • Insulin-like Growth Factor-I (IGF-1) • Prostatic Acid Phosphatase (PAP) • Prolactin • Prostate Specific Antigen, Total (Total PSA) • Prostate Specific Antigen, Free (Free PSA) • Thyroglobulin (Tg)	• Alpha Fetoprotein (AFP) • Beta-2-Microglobulin (B2-M) • CA 15-3 • CA 19-9 • CA 27.29 • CA 125 • Carcinoembryonic Antigen (CEA) • Ferritin • Human Chorionic Gonadotropin (hCG)/(β-hCG, Total hCG, Intact hCG) • Insulin-like Growth Factor-I (IGF-1) • Prostatic Acid Phosphatase (PAP) • Prolactin • Prostate Specific Antigen, Total (Total PSA) • Prostate Specific Antigen, Free (Free PSA) • Thyroglobulin (Tg) **Does not Contain:** • Her-2/neu • Human Epididymis Protein 4 (HE4)

8.0 Statement of Supporting Data

Real time stability studies were performed to establish Thawed and Opened, Thawed and unopened and Frozen Aliquot stability claims. Accelerated stability studies were performed for establishing the shelf life stability. The stabilities for Liquichek Tumor Marker Control are as follows

Thawed and Opened Stability	IGF-1: 15 days at 2 to 8°C CA 125: 10 days at 2 to 8°C All other analytes: 30 days at 2 to 8°C
Thawed and Unopened Stability	IGF-I, PAP: 35 days at 2 to 8°C Free PSA: 30 days at 2 to 8°C CA 125: 14 days at 2 to 8°C All other analytes: 60 days at 2 to 8°C
Frozen Aliquot Stability	All analytes: 30 days at -20°C to -70°C
Shelf Life stability:	28 months at -20 to -70°C

9.0 Conclusion

Based on the performance characteristics indicated above, Liquichek Tumor Marker Control is substantially equivalent to the predicate device (*K071675*).

All supporting data is retained on file at Bio-Rad Laboratories.