Summary of Safety and Effectiveness
Liquid Assayed Multiqual

1.0 Submitter
Bio-Rad Laboratories
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Regulatory Affairs Specialist
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Date of Summary Preparation
September 10, 2010

2.0 Device Identification
Product Trade Name: Liquid Assayed Multiqual
Common Name: Multi-Analyte Controls, (Assayed and unassayed)
Classifications: Class I
Product Code: JJY
Regulation Number: 21 CFR 862.1660

3.0 Device to Which Substantial Equivalence is Claimed
Liquid Assayed Multiqual
Bio-Rad Laboratories
Irvine, California
510 (k) Number: K043208

4.0 Description of Device
Liquid Assayed Multiqual is prepared from human serum to which purified biochemical material (tissue extracts of human and animal origin), chemicals, drugs, preservatives, and stabilizers have been added.

5.0 Intended Use
Liquid Assayed Multiqual 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.
6.0 **Comparison of the new device with the Predicate Device**

Liquid Assayed Multiquant claims substantial equivalence to the Liquid Assayed Multiquant currently in commercial distribution (K043208). Both of these controls are liquid human serum base with identical formulation. 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.**

<table>
<thead>
<tr>
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<tbody>
<tr>
<td>Intended Use</td>
<td>Liquid Assayed Multiquant 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.</td>
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<tr>
<td>Form</td>
<td>Liquid</td>
<td>Liquid</td>
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<tr>
<td>Matrix</td>
<td>Human serum based</td>
<td>Human serum based</td>
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</tbody>
</table>

**Similarities**

- Storage (Unopened): Until expiration date at -20°C to -60°C
  - Biurein, Direct
  - Cholesterol, Total
  - Creatine Kinase (CK)
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7.0 Statement of Supporting Data

Stability studies have been performed to determine the open vial stability and shelf life for the Liquid Assayed Multiqual. Product claims are as follows:

7.1 Open vial

5 days at 2 to 8°C

7.2 Thawed and Unopened:

30 days at 2 to 8°C, with the following exceptions: Direct Bilirubin 11 days, Triglycerides, HDL, Cholinesterase. Phosphorus 7 days. Total Bilirubin and Direct Bilirubin values may decrease, Alkaline Phosphatase activity may rise.

7.3 Shelf Life Stability

3 Years at -20°C to -50°C

7.4 Assignment of Values

The assigned values were derived from replicate analyses and are specific for each lot of product. The tests listed were performed by the manufacturer and/or independent laboratories using manufacturer supported reagents and a representative sampling of the product lot. Assigned values are presented as means and ±3SD ranges.

8.0 Conclusion

Liquid Assayed Multiqual (new device) is intended to be used for the same purposes as the predicate device, it has the same human serum matrix and performs similarly as the predicate device.

All supporting data is retained on file at Bio-Rad Laboratories.
Bio-Rad Diagnostics Group  
c/o Suzanne Parsons  
Regulatory Affairs/QA/QC Manager  
9500 Jeronimo Road  
Irvine, CA 92618-2017, USA

Re: k100727  
Trade/Device Name: Liquid Assayed Multiqual  
Regulation Number: 21 CFR 862.1660  
Regulation Name: Quality Control Material (Assayed and Unassayed)  
Regulatory Class: Class I, reserved  
Product Code: JJY  
Dated: August 27, 2010  
Received: September 3, 2010

Dear Ms. Parsons

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 advice for your device on our labeling regulation (21 CFR Parts 801 and 809), please contact the Office of In Vitro Diagnostic Device Evaluation and Safety at (301) 796-5450. 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 Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

[Signature]

Courtney Harper, Ph.D.
Director
Division of Chemistry and Toxicology
Office of In Vitro Diagnostic Device Evaluation and Safety
Center for Devices and Radiological Health

Enclosure
Indications for Use Form

510(k) Number (if known):  K100727

Device Name: Liquid Assayed Multiqual

Indications for Use: Liquid Assayed Multiqual 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.

Prescription Use  X  AND/OR  Over-The-Counter Use
(Part 21 CFR 801 Subpart D)  (21 CFR 801 Subpart C)

(Please do not write below this line—continue on another page of 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)  K100727