Bio-Rad Laboratories
Liquichek Tumor Markers Control
Premarket Notification Section 510(k)

1.0 DEVICE INFORMATION
Product Name: Liquichek Tumor Markers Control
Common Name: Clinical Chemistry Test Systems
Quality control material (assayed and unassayed).

2.0 MEDICAL DEVICE ESTABLISHMENT
Manufacturing Facility: Bio-Rad Laboratories
Address: 9500 Jeronimo Road
Irvine, California 92618
Telephone: 949-598-1200
Fax: 949-598-1557
Establishment Registration No.: 2016706

3.0 DEVICE CLASS
Classification: Class I
Product Code: JJY
Regulation Number: 21 CFR 862.1660

4.0 PERFORMANCE STANDARDS
None Require

5.0 PROPOSED LABELING
Included in this 510(k) notification is a copy of the proposed Liquichek Tumor Markers Control vial, box and insert labels (Appendices 3, 4 and 5).

6.0 STATEMENT OF SUBSTANTIAL EQUIVALENCE
Liquichek Tumor Markers Control is intended for use as an assayed quality control material to monitor the precision of laboratory testing procedures for the analytes listed in the package insert. This control is substantially equivalent to the following quality control material that is currently in the market:

Lyphochek Tumor Markers Control
Bio-Rad Laboratories
Irvine, California 92618
510 (k) Number: K011579
A copy of the product insert for the above product can be found in Appendix 7.

CONFIDENTIAL
7.0 **COMPARISON OF THE NEW DEVICE WITH THE PREDICATE DEVICE**

Liquichek Tumor Markers Control claims substantial equivalence to the Lyphochek Tumor Markers Control currently in commercial distribution (K011579).

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

<table>
<thead>
<tr>
<th>Characteristics</th>
<th><strong>Bio-Rad Laboratories</strong></th>
<th><strong>Bio-Rad Laboratories</strong></th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Liquichek Tumor Markers Control (New Device)</td>
<td>Lyphochek Tumor Markers Control (Predicate Device (K011579))</td>
</tr>
<tr>
<td></td>
<td><strong>Similarities</strong></td>
<td><strong>Differences</strong></td>
</tr>
<tr>
<td><strong>Intended Use</strong></td>
<td>Liquichek Tumor Markers Control is intended for use as an assayed quality control material to monitor the precision of laboratory testing procedures for the analytes listed in the package insert.</td>
<td>Lyphochek Tumor Markers Control is intended for use as an assayed quality control material to monitor the precision of laboratory testing procedures for the analytes listed in the package insert.</td>
</tr>
<tr>
<td><strong>Form</strong></td>
<td>Liquid</td>
<td>Lyophilized</td>
</tr>
<tr>
<td><strong>Matrix</strong></td>
<td>Human and animal serum albumin</td>
<td>Human serum</td>
</tr>
<tr>
<td><strong>Levels</strong></td>
<td>Level 1, 2 and 3</td>
<td>Level 1 and 2</td>
</tr>
<tr>
<td><strong>Preservatives</strong></td>
<td>Contains preservatives</td>
<td>Does not contain preservatives</td>
</tr>
<tr>
<td><strong>Storage (Unopened)</strong></td>
<td>-20°C to -70°C, Until expiration date</td>
<td>2°C to 8°C, Until expiration date</td>
</tr>
<tr>
<td><strong>Open Vial Claim / After reconstitution</strong></td>
<td>All analytes 30 days at 2 to 8°C.</td>
<td>All analytes 14 days at 2 to 8°C</td>
</tr>
<tr>
<td><strong>Exceptions</strong></td>
<td>Insulin-like Growth Factor-I (IGF-I) 15 days.</td>
<td>Ferritin and CA 27-29 6 days. ACTH, Free PSA, PSA, Calcitonin assay immediately.</td>
</tr>
<tr>
<td><strong>After reconstituting and freezing</strong></td>
<td>No claims</td>
<td>30 days at -10°C to -20°C</td>
</tr>
<tr>
<td><strong>Analytes</strong></td>
<td>Contains claim for the following:</td>
<td>Contains claim for the following:</td>
</tr>
<tr>
<td>* Alpha Fetoprotein</td>
<td>PAP</td>
<td>PAP</td>
</tr>
<tr>
<td>* Beta-2-Microglobulin</td>
<td>Proactin</td>
<td>Beta-2-Microglobulin</td>
</tr>
<tr>
<td>CA 15-3</td>
<td>Total PSA</td>
<td>CA 15-3</td>
</tr>
<tr>
<td>CA 19-9</td>
<td>Free PSA</td>
<td>CA 19-9</td>
</tr>
<tr>
<td>CA 27-29</td>
<td>Thyroglobulin</td>
<td>CA 27-29</td>
</tr>
<tr>
<td>CA 125</td>
<td>Insulin-like Growth Factor-I</td>
<td>CA 125</td>
</tr>
<tr>
<td>CEA</td>
<td></td>
<td>CEA</td>
</tr>
<tr>
<td>Ferritin</td>
<td></td>
<td>Ferritin</td>
</tr>
<tr>
<td>hCG (β-hCG, Total hCG, Intact hCG)</td>
<td></td>
<td>hCG hCG – Beta Subunit</td>
</tr>
<tr>
<td>Does not contain claim for the following:</td>
<td></td>
<td>Does not contain claim for the following:</td>
</tr>
<tr>
<td>* Aldosterone</td>
<td>CASA</td>
<td>* Thyroglobulin</td>
</tr>
<tr>
<td>* ACTH</td>
<td></td>
<td>* Neuro Specific Enolase</td>
</tr>
<tr>
<td>* CA 50</td>
<td></td>
<td>* Insulin-like Growth Factor-I</td>
</tr>
</tbody>
</table>

8.0 **STATEMENT OF SUPPORTING DATA**

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

- **Open vial Stability**: All analytes will be stable for 30 days at 2 to 8°C, with the following exception: Insulin-like Growth Factor-I (IGF-1) will be stable for 15 days.
- **Shelf Life**: 2 Years at -20°C to -70°C

All supporting data is retained on file at Bio-Rad Laboratories.
Attachment 2

Liquichek Tumor Markers Control
Summary of Safety and Effectiveness
Bio-Rad Laboratories
c/o Ms. Maria Zeballos
Regulatory Affairs Specialist
9500 Jeronimo Rd.
Irvine, CA 92618-2017

Re: k071675
Trade/Device Name: Liquichek Tumor Markers Control
Regulation Number: 21 CFR 862.1660
Regulation Name: Quality control material (assayed and unassayed)
Regulatory Class: Class I
Product Code: JJY
Dated: June 15, 2007
Received: June 19, 2007

Dear Ms. Zeballos:

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 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 Part 801); 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 (240) 276-0450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH’s Office of Surveillance and Biometric’s (OSB’s) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. 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 (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.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): K071675

Device Name: Liquichek Tumor Markers Control

Indications For Use: Liquichek Tumor Markers Control is intended for use as an assayed quality control material 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) K071675