Date of preparation of this summary: 8 August 2003

(2) Device trade or proprietary name: Roche COMBITROL PLUS B and Roche AUTOTROL PLUS B 
Muti Analyte Controls

Device common or usual name or classification name:
Multi Analyte Control Solution, All Types (Assayed and Unassayed)

<table>
<thead>
<tr>
<th>CLASSIFICATION</th>
</tr>
</thead>
<tbody>
<tr>
<td>PRODUCT NOMENCLATURE</td>
</tr>
<tr>
<td>MULTI-ANALYTE CONTROLS - ALL KINDS</td>
</tr>
</tbody>
</table>

(3) Substantial Equivalence
This device is substantially equivalent in function, safety and efficacy to currently marketed devices produced by Bionostics. In example:

Comparison of COMBITROL PLUS B and AUTOTROL PLUS B to predicate devices for substantial equivalency

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>Predicate Devices</th>
<th>Modified Device</th>
</tr>
</thead>
<tbody>
<tr>
<td>Name: Blood Gas, Electrolyte and CO-Oximetry Control</td>
<td>Blood Gas, Electrolyte, Metabolite Control</td>
<td>Roche COMBITROL PLUS B and Roche AUTOTROL PLUS B</td>
</tr>
<tr>
<td>510(k), Date: K913133, 09/27/1991</td>
<td>K972866, 08/28/1997</td>
<td></td>
</tr>
<tr>
<td>Number of levels: 3</td>
<td>3</td>
<td>3</td>
</tr>
<tr>
<td>Analytes: pH, blood gases, Na⁺, K⁺, Cl⁻, iCa++, tHb and Hb derivatives</td>
<td>pH, blood gases, Na⁺, K⁺, Li⁺, Cl⁻, iMg++, iCa++, Glucose, Lactate, BUN, Creatinine</td>
<td>pH, blood gases, Na⁺, K⁺, iCa++, Cl⁻, Li⁺, iMg++, Glucose, Lactate, BUN, Creatinine, tHb, Hb derivatives and bilirubin</td>
</tr>
<tr>
<td>Container: clear, glass ampoule</td>
<td>clear, glass ampoule</td>
<td>clear, glass ampoule</td>
</tr>
<tr>
<td>Fill volume: 2.5 mL</td>
<td>2.5 mL</td>
<td>1.7 mL</td>
</tr>
<tr>
<td>Color: Red</td>
<td></td>
<td>Red</td>
</tr>
</tbody>
</table>

* This summary of safety and effectiveness is submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.
(4) **Description of the new device**

COMBITROL PLUS B / AUTOTROL PLUS B is a specially formulated, three-level, aqueous liquid material intended for use to monitor all analytes measured by the Roche OMNI S Analyzer. COMBITROL PLUS B / AUTOTROL PLUS B provides a convenient method of performing periodic QC checks for laboratories selecting to measure liquid QC material as a part of their quality assurance program.

COMBITROL PLUS B / AUTOTROL PLUS B contains clinically relevant quantities of pH, PCO2, PO2, sodium, potassium, ionized calcium, chloride, glucose, lactate, urea, and hematocrit, and suitable concentrations of dyes to simulate clinically relevant values of bilirubin, hemoglobin and hemoglobin derivatives: O2Hb, COHb, MetHb and HHb. COMBITROL PLUS B / AUTOTROL PLUS B is a non-hazardous aqueous solution containing no biological materials.

(5) **Intended use of the device**

COMBITROL PLUS B / AUTOTROL PLUS B assayed controls are intended to be used to monitor and evaluate the analytical performance of the Roche OMNI S for analytes listed in the package insert.

(6) **Technological characteristics of the device.**

This material consists of buffered aqueous electrolyte solutions with clinically relevant concentrations of the targeted analytes, tonometered with precision gas mixtures of carbon dioxide and oxygen to achieve pH and blood gas values which span the range of values typical for such products with the same intended use. A mixture of dyes is used to simulate absorbance of hemoglobin derivatives and bilirubin. Hematocrit is simulated by conductivity.

(b) **Summary of non-clinical tests submitted with the premarket notification for the device.**

Tests were conducted to verify specific performance requirements:

- Real-time evaluation of products with essentially similar formulation and failure mode to support stability.
- Test precision

(b) **Summary of clinical tests submitted with the premarket notification for the device.**

N/A

(b) **Conclusions drawn from the clinical and non-clinical trials.**

Comparison of technological characteristics, formulation and intended use to predicate devices listed in this summary support the claim of substantial equivalence.
Ms. Kathleen Storro  
Senior Director, QA and Regulatory Affairs  
Bionostics, Inc.  
7 Jackson Road  
Devens, MA 01432  

Re: k032453  
Trade/Device Name: Roche COMBITROL PLUS B and  
Roche AUTOTROL PLUS B  
Regulation Number: 21 CFR 862.1660  
Regulation Name: Quality Control Material (Assayed and Unassayed).  
Regulatory Class: Class I  
Product Code: JJY  
Dated: August 8, 2003  
Received: August 15, 2003  

Dear Ms. Storro:  

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 I (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). Other general information on your responsibilities under the Act may be obtained 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, M.D., M.B.A.
Director
Office of In Vitro Diagnostic Device Evaluation and Safety
Center for Devices and Radiological Health

Enclosure
Device Name: Roche COMBITROL PLUS B and Roche AUTOTROL PLUS B

Indications for Use:
COMBITROL PLUS B / AUTOTROL PLUS B assayed controls are intended to be used to monitor and evaluate the analytical performance of the Roche OMNI S for analytes listed in the package insert.

For In Vitro Diagnostic Use

Carol Bennenski, Jena Cooper, OVM
Division Sign-Off

Office of In Vitro Diagnostic Device Evaluation and Safety

510(k) K03 2453

(Please do not write below this line - continue on another page if needed)

Prescription Use ✓ OR Over-The-Counter Use
(Per 21 CFR 801.109)

(Optional Format 1-2-96)