510(k) Summary - COBAS Integra Albumin Gen.2

Introduction
According to the requirements of 21 CFR 807.92, the following information provides sufficient detail to understand the basis for a determination of substantial equivalence.

Submitter name, address, contact
Roche Diagnostics Corporation
9115 Hague Rd
Indianapolis IN 46250
(317) 521-3831
Contact person: Sherri L. Coenen
Date prepared: September 24, 2003

Device Name
Proprietary name: Roche Diagnostics COBAS Integra Albumin Gen.2
Common name: Albumin Assay
Classification name: Albumin test system

Device description
The COBAS Integra Albumin Gen.2 is a colorimetric assay for the determination of albumin concentration in serum or plasma. At a pH value of 4.1, albumin displays a sufficiently cationic character to be able to bind with bromcresol green (BCG) to form a blue-green complex. The color intensity is directly proportional to the albumin concentration and can be determined photometrically.

Intended use
The cassette COBAS Integra Albumin Gen.2 (ALB2) contains an in vitro diagnostic reagent system intended for use on COBAS Integra systems for the quantitative determination of the albumin concentration in human serum and plasma.

Predicate Device
We claim substantial equivalence to the currently marketed COBAS Integra Albumin Assay. (K951595).
The following table describes the similarities and differences between the COBAS Integra Albumin Gen.2 and the predicate device.

<table>
<thead>
<tr>
<th>Topic</th>
<th>COBAS Integra Albumin (K951595)</th>
<th>COBAS Integra Albumin Gen.2 (Modified Device)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Intended Use</td>
<td>The cassette COBAS Integra Albumin (ALB) contains an in vitro diagnostic reagent system intended for use on COBAS Integra systems for the quantitative determination of the albumin concentration in serum and plasma.</td>
<td>The cassette COBAS Integra Albumin Gen.2 (ALB2) contains an in vitro diagnostic reagent system intended for use on COBAS Integra systems for the quantitative determination of the albumin concentration in serum and plasma.</td>
</tr>
<tr>
<td>Method</td>
<td>BCG colorimetric assay with endpoint method</td>
<td>Same</td>
</tr>
<tr>
<td>Sample type</td>
<td>Serum</td>
<td>Same</td>
</tr>
<tr>
<td></td>
<td>Heparin or EDTA plasma</td>
<td></td>
</tr>
<tr>
<td>Measuring range</td>
<td>0.08 - 60 g/L.</td>
<td>2 - 60 g/L</td>
</tr>
<tr>
<td>Expected values</td>
<td>Adults (18-60 yrs): 3.5 - 5.0 g/dL Adults (&gt; 60 yrs): 3.4 - 4.8 g/dL Newborn: 2.8 - 4.4 g/dL Children (4 days - 14 yrs): 3.8 - 5.4 g/dL Children (14 - 18 years): 3.2 - 4.5 g/dL</td>
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</tbody>
</table>
Ms. Sherri L. Coenen  
Regulatory Affairs Consultant  
Regulatory Submissions, Centralized Diagnostics  
Roche Diagnostics Corporation  
9115 Hague Road  
P.O. Box 50457  
Indianapolis, IN 46250-0457

Re:  k033009  
Trade/Device Name: COBAS Integra Albumin Gen.2  
Regulation Number: 21 CFR 862.1035  
Regulation Name: Albumin test system  
Regulatory Class: Class II  
Product Code: CIX  
Dated: September 24, 2003  
Received: September 26, 2003

Dear Ms. Coenen:

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,

Steven I. Gutman
Director
Office of In Vitro Diagnostic Device Evaluation and Safety
Center for Devices and Radiological Health

Enclosure
Indications for Use Statement

510(k) Number (if known): N/A K033009

Device Name: COBAS Integra Albumin Gen.2

Indications For Use:

The cassette COBAS Integra Albumin Gen.2 (ALB2) contains an in vitro diagnostic reagent system intended for use on COBAS Integra systems for the quantitative determination of the albumin concentration in human serum and plasma. Albumin measurements are used in the diagnosis and treatment of numerous diseases involving primarily the liver or kidneys.