Roche ONLINE Quinidine Assay

510(k) Summary

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.

1) Submitter name, address, contact

Roche Diagnostics Corporation
9115 Hague Rd.
Indianapolis, IN 46250
(317) 845-2000

Contact Person: Mike Flis

Date Prepared: July 28, 2003

2) Device name

Roche ONLINE TDM Quinidine

3) Predicate device

We claim substantial equivalence to the Roche COBAS INTEGRA Quinidine [K951595].

4) Device Description

The assay is a homogeneous immunoassay based on the principle of measuring changes in scattered light or absorbance which result when activated microparticles aggregate. The microparticles are coated with quinidine and rapidly aggregate in the presence of a quinidine antibody solution. When a sample containing quinidine is introduced, the aggregation reaction is partially inhibited, slowing the rate of the aggregation process. Antibody bound to sample drug is no longer available to promote microparticle aggregation, and subsequent particle lattice formulation is inhibited. Thus, a classic inhibition curve with respect to quinidine concentration is obtained, with the maximum rate of aggregation at the lowest quinidine concentration. By monitoring the change in scattered light or absorbance, a concentration-dependent curve is obtained.

Continued on next page
510(k) Summary, Continued

5) Intended use
For the quantitative determination of quinidine in human serum or plasma on automated clinical chemistry analyzers.

6) Comparison to predicate device
The Roche ONLINE TDM Quinidine was evaluated for several performance characteristics, including precision, lower detection limit, method comparison, specificity, and interfering substances. All of the evaluation studies gave acceptable results compared to the predicate device. These experiments provide evidence that the Roche ONLINE TDM Quinidine is substantially equivalent to the currently marketed Roche COBAS INTEGRA Quinidine Assay. The following table presents the precision and method comparison results.

<table>
<thead>
<tr>
<th>Roche ONLINE TDM Quinidine</th>
<th>Roche COBAS INTEGRA Quinidine, (Predicate labeling)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Versus Roche COBAS INTEGRA Quinidine Assay (predicate device)</td>
<td>Versus Enzyme Immunoassay</td>
</tr>
<tr>
<td>N = 150</td>
<td>N = 154</td>
</tr>
<tr>
<td>Y = 1.054X - 0.036</td>
<td>Y = 0.941X - 0.024</td>
</tr>
<tr>
<td>R = 0.991</td>
<td>R = 0.991</td>
</tr>
<tr>
<td>Range = 0.22 to 7.04 µg/mL</td>
<td>Range = 0.16 to 5.7 µg/mL</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>NCCLS Precision:</th>
<th>Level 1</th>
<th>Level 2</th>
<th>Level 3</th>
<th>Level 1</th>
<th>Level 2</th>
<th>Level 3</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mean (µg/mL)</td>
<td>0.93</td>
<td>2.87</td>
<td>4.61</td>
<td>1.35</td>
<td>3.47</td>
<td>5.42</td>
</tr>
<tr>
<td>CV% (within-run)</td>
<td>2.0</td>
<td>1.3</td>
<td>1.2</td>
<td>2.1</td>
<td>2.2</td>
<td>2.0</td>
</tr>
<tr>
<td>CV% (total)</td>
<td>3.9</td>
<td>2.7</td>
<td>2.7</td>
<td>3.2</td>
<td>3.5</td>
<td>3.2</td>
</tr>
</tbody>
</table>
Mr. Mike Flis  
Regulatory Affairs Principal  
Roche Diagnostics Corporation  
9115 Hague Road  
P.O. Box 50457  
Indianapolis, In 46250-0457  

Re:  k032332  
Trade/Device Name: Roche ONLINE TDM Quinidine Assay  
Regulation Number: 21 CFR 862.3320  
Regulation Name: Digoxin test system  
Regulatory Class: Class II  
Product Code: LBZ  
Dated: October 31, 2003  
Received: November 4, 2003  

Dear Mr. Flis:

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, M.D., M.B.A.
Director
Office of In Vitro Diagnostic Device Evaluation and Safety
Center for Devices and Radiological Health

Enclosure
Roche Diagnostics Corporation

510(k) Number (if known):
Device Name: Roche ONLINE TDM Quinidine Assay

Indications for Use:

The Roche ONLINE TDM Quinidine assay is for the quantitative determination of quinidine in human serum or plasma on automated clinical chemistry analyzers. Quinidine is used for the prevention and treatment of ventricular arrhythmias, junctional (nodal) arrhythmias, and supraventricular (atrial) arrhythmias. The quinidine dosage required to achieve therapeutic serum levels is dependent on the drug formulation, patient age, and individual variability in absorption and metabolism. The proposed labeling indicates the Roche/Hitachi 911, 912, 917, and Modular P analyzers can be used with the Roche ONLINE Quinidine reagent kits.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

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

Division Sign-Off

Office of In Vitro Diagnostic Device Evaluation and Safety

510(k)  K032337