This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92

Submitter's name: Diazyme Laboratories
Submitter's address: 12889 Gregg Court
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Date the Summary was Prepared: September 24, 2007, June 5, 2008, and July 8, 2008

Name of the Device: Diazyme Apolipoprotein A-I Assay
Trade Name: Diazyme Apolipoprotein A-I Assay
Common/Usual Name: Apolipoprotein A-I Test System
Device Classification Name: Lipoprotein test system
Product code: MSJ (reagent), JIT (calibrator), JJX (control)
Submission Type: 510k

Regulation Number: 862.1475(reagent), 862.1150(calibrator), 862.1660(control)
Device Class: II (reagent), II (calibrator), I Reserved (control)
Predicate Device: For the Alpha-1-lipoprotein Immunological Test System Lipoprotein test system, we are claiming equivalence [807.92(a) (3) to K-ASSAY APO AI ASSAY (k993345) manufactured by Kamiya Biomedical Company
Substantial Equivalence Information

1. Predicate device name(s):
   K-Assay Apo Al Assay

2. Predicate 510(k) number(s):
   K993345

3. Comparison with predicate:

   Indications for Use

<table>
<thead>
<tr>
<th>Diazyme Apolipoprotein A-I Assay</th>
<th>K-Assay Apo Al Assay</th>
<th>Equivalency</th>
</tr>
</thead>
<tbody>
<tr>
<td>The Diazyme Apolipoprotein A-I Assay is intended for the in vitro quantitative determination of apolipoprotein A-I (Apo A-I) in serum. It can be used as an aid for assessing the risk of coronary artery disease.</td>
<td>For the quantitative determination of human Apolipoprotein A-I (Apo Al) in serum by immunoturbidimetric assay.</td>
<td>Same</td>
</tr>
</tbody>
</table>

   Principle

<table>
<thead>
<tr>
<th>Diazyme Apolipoprotein A-I Assay</th>
<th>K-Assay Apo Al Assay</th>
<th>Equivalency</th>
</tr>
</thead>
<tbody>
<tr>
<td>This method is based on the reaction of a sample containing human Apo A-I and specific antiserum to form an insoluble complex which can be measured turbidimetrically at 340nm. By constructing a standard curve from the absorbance of standards the concentration of Apo A-I can be determined.</td>
<td>This method quantifies Apolipoprotein A-I based on immunoturbidimetric assay. The reagent uses a goat polyclonal antibody specific for human Apolipoprotein AI. The antibody binds to the Apo AI in the serum forming light scattering immune complexes, which increase the turbidity of the sample. Since the turbidity is proportional to the amount of Apo AI in the sample, the Apolipoprotein AI concentration can be determined by measuring this increase in turbidity. The increase in turbidity is measured at 800 nm. Apolipoprotein AI in the sample is quantitatively determined.</td>
<td>Similar</td>
</tr>
</tbody>
</table>

   Test Objective

<table>
<thead>
<tr>
<th>Diazyme Apolipoprotein A-I Assay</th>
<th>K-Assay Apo Al Assay</th>
<th>Equivalency</th>
</tr>
</thead>
<tbody>
<tr>
<td>The Diazyme LDL-Cholesterol Assay is intended for the in vitro quantitative determination of Low Density Lipoprotein Cholesterol in human serum or plasma.</td>
<td>For the quantitative determination of human Apolipoprotein Al (Apo Al) in serum by immunoturbidimetric assay.</td>
<td>Same</td>
</tr>
</tbody>
</table>

   Type of Test

<table>
<thead>
<tr>
<th>Diazyme Apolipoprotein A-I Assay</th>
<th>K-Assay Apo Al Assay</th>
<th>Equivalency</th>
</tr>
</thead>
<tbody>
<tr>
<td>Quantitative</td>
<td>Quantitative</td>
<td>Same</td>
</tr>
</tbody>
</table>
### Specimen Type

<table>
<thead>
<tr>
<th>Specimen Type</th>
<th>Diazyme Apolipoprotein A-I Assay</th>
<th>K-Assay Apo Al Assay</th>
<th>Equivalency</th>
</tr>
</thead>
<tbody>
<tr>
<td>Human serum</td>
<td>Human serum</td>
<td>Same</td>
<td></td>
</tr>
</tbody>
</table>

### Product Type

<table>
<thead>
<tr>
<th>Product Type</th>
<th>Diazyme Apolipoprotein A-I Assay</th>
<th>K-Assay Apo Al Assay</th>
<th>Equivalency</th>
</tr>
</thead>
<tbody>
<tr>
<td>Calibrator, Reagent, Instrument</td>
<td>Calibrator, Reagent, Instrument</td>
<td>Same</td>
<td></td>
</tr>
</tbody>
</table>

### Performance

<table>
<thead>
<tr>
<th>Diazyme Apolipoprotein A-I Assay</th>
<th>K-Assay Apo Al Assay</th>
</tr>
</thead>
<tbody>
<tr>
<td>Reportable Range: Serum: 20-228 mg/dL</td>
<td>Reportable Range: Serum: 20 - 300 mg/dL</td>
</tr>
<tr>
<td>Precision/Serum: Within Run: 0.6% -0.9% Total: 1.8%–3.3%</td>
<td>Precision/Serum: Within Run: 1.51% -1.87% Total: 1.05%–1.57%</td>
</tr>
<tr>
<td>Accuracy/Serum: Correlation Coefficient: 0.9789 Slope/Intercept: y = 0.91 + 2.813</td>
<td>Accuracy/Serum: Correlation Coefficient: 0.970 Slope/Intercept: y = 0.980x + 4.776 mg/dL</td>
</tr>
</tbody>
</table>

### Calibrator Comparison

<table>
<thead>
<tr>
<th>Diazyme Apolipoprotein A-I Assay</th>
<th>K-Assay Apo Al Assay</th>
<th>Equivalency</th>
</tr>
</thead>
<tbody>
<tr>
<td>Lyophilized form</td>
<td>Lyophilized form</td>
<td>Same</td>
</tr>
<tr>
<td>Diazyme Apolipoprotein A-I calibrator value is traceable to the WHO International Reference Material for Apo Al, Sp1-01.</td>
<td>K-Assay Apo Al calibrator value is traceable to the WHO International Reference Material for Apo Al, Sp1-01.</td>
<td>Same</td>
</tr>
</tbody>
</table>
General Atomics
Diazyme Laboratories
c/o Mr. Charles Yu, Quality System Manager
12889 Gregg Court
Poway, California 92064

JUL 16 2008

Re: k072977
Trade Name: Diazyme Apolipoprotein A-I Assay;
Diazyme Apolipoprotein A-I Calibrator, and
Diazyme Apolipoprotein A-I Control,
Regulation Number: 21 CFR 862.1475
Regulation Name: Lipoprotein test system
Regulatory Class: Class I, meets the limitation to exemption in 862.9(c)(4)
Product Code: MSJ, JIT, JJX
Dated: June 5, 2008
Received: June 17, 2008

Dear Mr. Yu:

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 (240) 276-0490. 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 (240) 276-3150 or at its Internet address at http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Jean M. Cooper, M.S., D.V.M.
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

510(k) Number: K072977

Device Name: Diazyme Apolipoprotein A-I Assay

Indications for Use: The Diazyme Apolipoprotein A-I Assay is intended for the in vitro quantitative determination of apolipoprotein A-I (apo A-I) in serum. It can be used as an aid for assessing the risk of coronary artery disease. For in vitro Diagnostic use.


Controls: To monitor the performance of Diazyme Apolipoprotein A-I Assay in serum. For in vitro Diagnostic Use.