K073488

MAR - 7 2008

510(k) Summary

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 Poway, CA 92064 USA
Name of Contact Person:	Charles Yu Diazyme Laboratories 12889 Gregg Court Poway, CA 92064 Phone: 858-455-4761 Fax: 858-455-4750
Date the Summary was Prepared:	September 24, 2007
Name of the Device	Diazyme Apolipoprotein B Assay
Trade Name:	Diazyme Apolipoprotein B Assay
Common/Usual Name	Apolipoprotein B Test System
Device Classification Name	Alpha-1-lipoprotein Immunological Test System

Reagents

Product code:	MSJ
Submission Type	510k
Regulation Number	862.1475
Device Class	II

Calibrator

Product code:	JIT
Submission Type	510k
Regulation Number	862.1150
Device Class	II

Control

Product code:	JJX
Submission Type	510k
Regulation Number	862.1660
Device Class	I Reserved

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 B ASSAY (k993354) manufactured by Kamiya Biomedical Company

Substantial Equivalence Information

1. **Predicate device name(s):**

   K-Assay Apo B Assay

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

   K993354

3. **Comparison with predicate:**

Indications for Use

Diazyme Apolipoprotein B Assay	K-Assay Apo B Assay	Equivalency
The Diazyme Apolipoprotein B Assay is intended for the quantitative determination of apolipoprotein B (apo B) in serum. It can be used as an aid for assessing the risk of coronary artery disease.	For the quantitative determination of human Apolipoprotein B (Apo B) in serum by immunoturbidimetric assay.	Same

Principle

Diazyme Apolipoprotein B Assay	K-Assay B Assay	Equivalency
This method is based on the reaction of a sample containing human Apo B and a 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 B can be determined.	This method quantifies Apolipoprotein AI based on immunoturbidimetric assay. The reagent uses a goat polyclonal antibody specific for human Apolipoprotein B. The antibody binds to the Apo B 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 B in the sample, the Apolipoprotein B concentration can be determined by measuring this increase in turbidity. The increase in turbidity is measured at 600 nm. Apolipoprotein B in the sample is quantitatively determined.	Similar

Test Objective

Diazyme Apolipoprotein B Assay	K-Assay Apo B Assay	Equivalency
The Diazyme Apolipoprotein B Assay is intended for the quantitative determination of apolipoprotein B (apo B) in serum. It can be used as an aid for assessing the risk of coronary artery disease.	For the quantitative determination of human Apolipoprotein B (Apo B) in serum by immunoturbidimetric assay.	Same

Type of Test

Diazyme Apolipoprotein B Assay	K-Assay Apo B Assay	Equivalency

Quantitative	Quantitative	Same

Specimen Type

Diazyme Apolipoprotein B Assay	K-Assay Apo B Assay	Equivalency
Human serum	Human serum	Same

Product Type

Diazyme Apolipoprotein B Assay	K-Assay Apo B Assay	Equivalency
Calibrator, Reagent, Instrument	Calibrator, Reagent, Instrument	Same

Performance

Diazyme Apolipoprotein B Assay	K-Assay Apo B Assay
Reportable Range: Serum: **25.0 – 160 mg/dL** Precision/Serum: Within Run: **1.2% -1.4%** Total: **2.1%–4.8%** Accuracy/Serum: Correlation Coefficient: **0.9864** Slope/Intercept: **y = 1.0143x – 4.3806 mg/dL**	Reportable Range: Serum: **25 – 250 mg/dL** Precision/Serum: Within Run: **1.44% -2.12%** Total: **1.09%–2.33%** Accuracy/Serum: Correlation Coefficient: **0.885** Slope/Intercept: **y = 1.442x + 0.00 mg/dL**

Calibrator Comparison

Diazyme Apolipoprotein B Assay	K-Assay Apo B Assay	Equivalency
Lyophilized form	Lyophilized form	Same
Diazyme Apolipoprotein B calibrator value is traceable to the WHO/IFCC Reference Standard.	K-Assay Apo B calibrator value is traceable to the WHO International Reference Material for Apo B, SP3-07.	Same

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

MAR - 7 2008

General Atomics
Diazyme Laboratories Division,
c/o Mr. Charles Yu
Quality System Manager
12889 Gregg Court
Poway, CA 92064

Re: k073488
Trade Name: Diazyme Apolipoprotein B Assay
Regulation Number: 21 CFR 862.1475
Regulation Name: Lipoprotein test system
Regulatory Class: Class II
Product Codes: MSJ, JIT, JJX
Dated: February 21, 2008
Received: February 22, 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.

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: K073488

Device Name: Diazyme Apolipoprotein B Assay

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

Calibrator: For calibration of the Diazyme Apolipoprotein B Assay in serum. For *in vitro* Diagnostic Use.

Controls: To monitor the performance of Diazyme Apolipoprotein B Assay in serum. For *in vitro* Diagnostic Use.

Prescription Use ___X___ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 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) K073488