SEP 1 1 2006

510(k) Summary
diaDexus PLAC® Test

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.

The assigned 510(k) number is: k062234

General Information

Name and Address of Applicant: diaDexus, Inc.
343 Oyster Point Blvd.
South San Francisco, CA 94080

Device Trade Name: diaDexus PLAC® test

Generic Name: Enzyme Immunoassay for the Quantitative Determination of Lp-PLA_2 (Lipoprotein-Associated Phospholipase A_2) in Human Plasma and Serum

Intended Use

The diaDexus PLAC® test is an enzyme immunoassay for the quantitative determination of Lp-PLA_2 (lipoprotein-associated phospholipase A_2) in human plasma and serum, to be used in conjunction with clinical evaluation and patient risk assessment as an aid in predicting risk for coronary heart disease, and ischemic stroke associated with atherosclerosis.

Device Description

The diaDexus PLAC® test kit contains Lp-PLA_2 calibrators, monoclonal anti-Lp-PLA_2 (4B4) antibody conjugated to horseradish peroxidase, monoclonal anti-Lp-PLA_2 (2C10) antibody-coated microwell strips with a stripwell frame, various buffers and related reagents, and a package insert. Each stripwell can be used for performing only one set of tests (i.e. single use). One plate may accommodate up to 40 clinical samples when assayed in duplicate. The kit expiration date and storage conditions are indicated on the package.

The diaDexus PLAC® test is based on the standard principle of a sandwich enzyme immunoassay using two specific monoclonal antibodies. A set of Lp-PLA_2 calibrators is used to plot a standard curve of absorbance (y-axis) versus Lp-PLA_2 concentration in ng/mL (x-axis) from which the Lp-PLA_2 concentration in the test sample can be determined. The concentration of Lp-PLA_2 in each sample and control is then interpolated from the standard curve using a point-to-point curve fit with appropriate calibration curve fitting software.

Characterization of Rare Reagents

Antigen

The antigen used in the diaDexus enzyme immunoassay PLAC® test is purified recombinant Lp-PLA_2 (DDX-RA). Antigen preparations were characterized using SDS-polyacrylamide gels under reducing and non-reducing conditions and Western blot analysis using an anti-Lp-PLA_2 antibody, to demonstrate consistency with the molecular weight of the antigen reported in the literature.

Antibodies

The monoclonal anti-Lp-PLA_2 antibodies used in the preparation of the coated microwell strips (2C10) and conjugate (4B4) were characterized for purity and reactivity in a series of procedures including Paragon gel electrophoresis, SDS-PAGE, size exclusion chromatography, isotyping and enzyme immunoassay. These results demonstrated that the monoclonal antibodies bind to the Lp-PLA_2 antigen quantitatively and specifically.

Performance Characteristics – Analytical

Analytical Sensitivity (Detection Limit)

The minimum detection limit is 2.4 ng/mL, as calculated by interpolation of the mean plus two standard deviations of 16 replicates of the 0 ng/mL Lp-PLA_2 calibrator.

Linearity/Assay Range

120 – 782 ng/mL

Interfering Substances

No appreciable interference from the addition of the following substances at the noted concentrations:

- Total Albumin ~6500 mg/dL
- Bilirubin 20 mg/dL
- Cholesterol 500 mg/dL
- Hemoglobin 1250 mg/dL
- Triglycerides 3000 mg/dL

Precision

Intra-assay precision (n=80) ranged from 4.3 %CV to 6.3 %CV throughout assay range.

Total precision (n=80) ranged from 5.7 %CV to 11.0 %CV throughout assay range.

Correlation

The modified PLAC test compared to the cleared PLAC test in a correlation regression resulted in an r value of 0.91 with a slope of 1.02.

Performance Characteristics – Clinical

No new clinical data was generated. The modified PLAC test has the same performance characteristics and clinical utility as the cleared PLAC test (k050523).

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

SEP 11 2006

Robert L. Wolfert, Ph.D.
Executive Vice President of Diagnostics
diaDexus, Inc.
343 Oyster Point Blvd.
South San Francisco, CA 94080

Re: k062234
Trade/Device Name: diaDexus PLAC® Test
Regulation Number: 21 CFR 866.5600
Regulation Name: Low-density lipoprotein immunological test system
Regulatory Class: Class II
Product Code: NOE
Dated: August 1, 2006
Received: August 23, 2006

Dear Dr. Wolfert:

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) 276-0484. 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/industry/support/index.html.

Sincerely yours,

Alberto Gutierrez, Ph.D.
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: k062234

Device Name: diaDexus PLAC® Test

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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) k062234