DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

DIADEXUS, INC.
C/O LORRY WEAVER HUFFMAN
MYRAQA, INC.
3 LAGOON DR. SUITE 280
REDWOOD SHORES CA 94065

December 15, 2014

Re: K141575
Trade/Device Name: PLAC® Test for Lp-PLA$_2$ Activity
Lp-PLA$_2$ Activity Test Calibrators
Lp-PLA$_2$ Activity Test Controls
Regulation Number: 21 CFR 866.5600
Regulation Name: Low-density lipoprotein immunological test system
Regulatory Class: II
Product Code: NOE, JIT, JJX
Dated: October 30, 2014
Received: November 3, 2014

Dear Ms. Lorry Huffman:

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. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. 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); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the

electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulations (21 CFR Parts 801 and 809), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Katherine Serrano -S

For: Courtney H. Lias, Ph.D.
Director
Division of Chemistry and Toxicology Devices
Office of In Vitro Diagnostics
and Radiological Health
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K141575

Device Name
PLAC® Test for Lp-PLA2 Activity

Indications for Use *(Describe)*
The PLAC® Test for Lp-PLA2 Activity is an enzyme assay for the in vitro quantitative determination of Lp-PLA2 (lipoprotein-associated phospholipase A2) activity in EDTA-plasma and serum on automated clinical chemistry analyzers. Lp-PLA2 activity is to be used in conjunction with clinical evaluation and patient risk assessment as an aid in predicting risk of coronary heart disease (CHD) in patients with no prior history of cardiovascular events.

The Lp-PLA2 Activity Test Calibrators are intended to establish points of reference that are used in the determination of values in the measurement of Lp-PLA2 activity by the PLAC® Test for Lp-PLA2 Activity.

The Lp-PLA2 Activity Test Controls are intended for use as a quality control tool to monitor the performance within the clinical range of the PLAC® Test for Lp-PLA2 Activity, an enzyme assay for the quantitative determination of Lp-PLA2 activity

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

510(k) Summary - PLAC® Test for Lp-PLA$_2$ Activity

1. Submitter Name:

diaDexus, Inc.

349 Oyster Point Blvd.

South San Francisco, CA 94080

Contact: Emi Zychlinsky, Ph.D.

Telephone: 650-246-6459

2. Correspondent/Contact

Lorry Weaver Huffman, Senior Director

Myraqa, Inc.

3 Lagoon Dr., Suite 280

Redwood Shores, CA 94065

Phone: 1 (650) 730-5030

Mobile: 1 (916) 812-3047

Fax: 1 (916) 638-2647

E-mail: lorry@myraqa.com

3. Date Prepared: December 05, 2014

4. Device Name

Trade Name (Proprietary Name):	PLAC® Test for Lp-PLA$_2$ Activity Lp-PLA$_2$ Activity Test Calibrators Lp-PLA$_2$ Activity Test Controls
Common Name (Usual Name):	PLAC Activity
Panel:	Immunology
Measurand:	Lipoprotein-Associated Phospholipase A$_2$ (Lp-PLA$_2$)
Sample Type:	EDTA-plasma or serum
Type of Test:	Enzyme activity rate of change using a standard curve

Product	Regulation	Description	Product Code
PLAC® Test for Lp-PLA$_2$ Activity	866.5600	Test, system, immunoassay, lipoprotein-associated phospholipase A2	NOE
Lp-PLA$_2$ Activity Test Calibrators	862.1150	Calibrators, Secondary	JIT
Lp-PLA$_2$ Activity Test Controls	862.1660	Quality Control Material (assayed and unassayed)	JJX

5. Predicate Devices: K030477 - PLAC® Test

6. Device Description:

The PLAC® Test for Lp-PLA$_2$ Activity consists of the reagents, Lp-PLA$_2$ Activity Test Calibrators and Lp-PLA$_2$ Activity Test Controls for the measurement of Lp-PLA$_2$ activity in EDTA-plasma or serum on automated clinical laboratory analyzers.

Lp-PLA$_2$, in plasma or serum, hydrolyzes the sn-2 position of the substrate, 1-myristoyl-2-(4-nitrophenylsuccinyl) phosphatidylcholine, producing a colored reaction product, 4-nitrophenol. The rate of formation of 4-nitrophenol is measured spectrophotometrically for 8.5 minutes and the Lp-PLA$_2$ activity is calculated from the rate of change in absorbance. A set of five Lp-PLA$_2$ calibrators is used to generate a standard curve fit of change in absorbance versus Lp-PLA$_2$ activity level in nmol/min/mL from which the sample Lp-PLA$_2$ activity is derived.

The PLAC® Test for Lp-PLA$_2$ Activity also includes controls. Controls should be included in each run or in accordance with the user's laboratory's quality control policies.

7. Intended Use:

The PLAC® Test for Lp-PLA$_2$ Activity is an enzyme assay for the *in vitro* quantitative determination of Lp-PLA$_2$ (lipoprotein-associated phospholipase A$_2$) activity in EDTA-plasma and serum on automated clinical chemistry analyzers. Lp-PLA$_2$ activity is to be used in conjunction with clinical evaluation and patient risk assessment as an aid in predicting risk of coronary heart disease (CHD) in patients with no prior history of cardiovascular events.

The Lp-PLA$_2$ Activity Test Calibrators are intended to establish points of reference that are used in the determination of values in the measurement of Lp-PLA$_2$ activity by the PLAC® Test for Lp-PLA$_2$ Activity.

The Lp-PLA$_2$ Activity Test Controls are intended for use as a quality control tool to monitor the performance within the clinical range of the PLAC® Test for Lp-PLA$_2$ Activity, an enzyme assay for the quantitative determination of Lp-PLA$_2$ activity.

8. Summary of Technological Characteristics Compared to the Predicate Device:

The technological characteristics of the predicate device *diaDexus PLAC® Test,* 510(k) number K030477, differs in detection method from the device subject of this 510(k), *diaDexus PLAC® Test for Lp-PLA$_2$ Activity*. In principle, both assays measure Lp-PLA$_2$, however the predicate device measures concentration (ng/mL) and the subject assay measures enzymatic activity (nmol/min/mL).

The PLAC® Test for Lp-PLA$_2$ Activity is for *in vitro* diagnostic use for quantitative determination of Lp-PLA$_2$ activity. In the PLAC® Test for Lp-PLA$_2$ Activity, Lp-PLA$_2$ in plasma or serum, hydrolyzes the sn-2 position of the substrate, 1-myristoyl-2-(4-nitrophenylsuccinyl) phosphatidylcholine, producing 4-nitrophenyl succinate. The latter is immediately further hydrolyzed to produce the colored reaction product, 4-nitrophenol. The rate of formation of 4-nitrophenol is measured spectrophotometrically at 410 nm and the Lp-PLA$_2$ activity is calculated from the rate of change in absorbance. The predicate PLAC® Test is an ELISA immunoassay based on the principle of a sandwich enzyme immunoassay using two specific monoclonal antibodies for the direct measurement of Lp-PLA$_2$ concentration. Absorbance of the colored by-product from the enzymatic turnover of the substrate by the enzyme labeled on the detection antibody is measured spectrophotometrically at 450 nm and is directly proportional to the concentration of Lp-PLA$_2$ present.

The performance testing provided in this 510(k) is sufficient to demonstrate that PLAC® Test for Lp-PLA$_2$ Activity is substantially equivalent to the legally marketed predicate device, diaDexus PLAC® Test, K030477. The comparison of assays similarities and differences are shown in Table 1.

Table 1. Comparison of Assays

Attribute	(Predicate Devices) PLAC® Test (K030477)	(Subject Device) PLAC® Test for Lp-PLA$_2$ Activity
REAGENT KIT Intended Use	The PLAC® Test is an enzyme immunoassay for the quantitative determination of Lp-PLA$_2$ (lipoprotein-associated phospholipase A$_2$) in human plasma, to be used in conjunction with clinical evaluation and patient risk assessment as an aid in predicting risk for coronary heart disease.	The PLAC® Test for Lp-PLA$_2$ Activity is an enzyme assay for the *in vitro* quantitative determination of Lp-PLA$_2$ (lipoprotein-associated phospholipase A$_2$) activity in EDTA-plasma and serum on automated clinical chemistry analyzers. Lp-PLA$_2$ activity is to be used in conjunction with clinical evaluation and patient risk assessment as an aid in predicting risk of coronary heart disease (CHD) in patients with no prior history of cardiovascular events.
REAGENT KIT Classification Code	**NOE** - Test, system, immunoassay, lipoprotein-associated phospholipase A2	Same
CALIBRATORS Intended Use	The PLAC® Test Calibrators are intended to establish points of reference that are used in the determination of values in the measurement of Lp-PLA$_2$ by the PLAC® Test.	The Lp-PLA$_2$ Activity Test Calibrators are intended to establish points of reference that are used in the determination of values in the measurement of Lp-PLA$_2$ by the PLAC® Test for Lp-PLA$_2$ Activity.
CALIBRATORS Classification Code	**JIT** - Calibrators, Secondary	Same
CONTROLS Intended Use	The Lp-PLA$_2$ Controls are intended for use as a quality control tool to monitor the performance within the clinical range of the PLAC® Test, an immunoassay for the quantitative determination of Lp-PLA$_2$.	The Lp-PLA$_2$ Activity Test Controls are intended for use as a quality control tool to monitor the performance within the clinical range of the PLAC® Test for Lp-PLA$_2$ Activity, an enzyme assay for the quantitative determination of Lp-PLA$_2$ activity.

Attribute	(Predicate Devices) PLAC® Test (K030477)	(Subject Device) PLAC® Test for Lp-PLA$_2$ Activity
CONTROLS Classification Code	**JJX** - Enzyme controls (assayed and unassayed)	Same
Sample Source	EDTA plasma	Serum EDTA plasma
Assay method	Enzyme immunoassay (ELISA)	Enzyme kinetics activity rate of change using a standard curve
Measurement units	Concentration, ng/mL	Activity, nmol/min/mL
Analyte	Lp-PLA$_2$	Same
Test Reagents	• Anti-Lp-PLA$_2$ mAb coated stripwells • Enzyme conjugate anti-Lp-PLA$_2$ mAb-HRP • TMB substrate • Stop solution • Assay buffer • Reconstitution buffer • Sample diluent	• R1: Buffer • R2: Lp-PLA$_2$ Substrate, 1-myristoyl-2-(4-nitrophenylsuccinyl) phosphatidylcholine
Calibration materials	A set of calibrators made with recombinant Lp-PLA$_2$ protein in a protein matrix	A set of calibrators made with recombinant Lp-PLA$_2$ protein in a protein buffered matrix
Control materials	2 levels recombinant Lp-PLA$_2$ protein in a stabilizing diluent	Same
Sample Preparation	Sample diluent is added to the sample	No sample preparation is required
Instrument reader	Microtiter plate reader	Automated clinical chemistry analyzer

9. Summary of Non-clinical Performance Testing as Basis for Substantial Equivalence

Studies were conducted to evaluate the performance characteristics of the PLAC® Test for Lp-PLA$_2$ Activity. The studies include precision, analytical sensitivity (limit of detection/limit of the blank/limit of quantitation), linearity, recovery, interfering substances, specimen handling, stability, and matrix comparison.

Precision

The precision of the PLAC® Test for Lp-PLA$_2$ Activity was evaluated on one Beckman Coulter (Olympus) AU400® Clinical Chemistry Analyzer and three (3) kit lots according to CLSI EP5-A2. Four native plasma samples, kit control low, and kit control high with known amounts of Lp-PLA$_2$ activity values ranging from 111 to 321 nmol/min/mL were tested with 2 replicates per run, 2 runs per day for 20 days. Total precision CV's for all kit lots and test samples were < 3%.

Table 2 summarizes the results of the precision studies performed for the PLAC® Test for Lp-PLA$_2$ Activity.

Table 2 – Precision Results from Three Kit Lots

			Within-Run (Repeatability)		Between-Run		Between-Day		Total*	
Lot	**Sample**	**Mean (nmol/min/mL) N=80**	**SD**	**%CV**	**SD**	**%CV**	**SD**	**%CV**	**SD**	**%CV**
Acceptance Criteria				**≤5%**						**≤8%**
Lot 1	Kit Control Low	122.0	1.90	1.6%	2.59	2.1%	0.00[1]	0.0%	3.21	2.6%
	Kit Control High	303.8	4.57	1.5%	4.74	1.6%	0.00	0.0%	6.59	2.2%
	Sample 1	117.1	1.68	1.4%	1.55	1.3%	0.00	0.0%	2.29	2.0%
	Sample 2	213.1	2.79	1.3%	3.16	1.5%	0.88	0.4%	4.31	2.0%
	Sample 3	249.8	4.63	1.9%	3.18	1.3%	2.05	0.8%	5.98	2.4%
	Sample 4	320.8	3.52	1.1%	3.49	1.1%	0.00	0.0%	4.96	1.5%

[1] Values of 0.0 are actual calculated results rounded for values <0.05.

			Within-Run (Repeatability)		Between-Run		Between-Day		Total*	
Lot	**Sample**	**Mean (nmol/min/mL) N=80**	**SD**	**%CV**	**SD**	**%CV**	**SD**	**%CV**	**SD**	**%CV**
Acceptance Criteria				**≤5%**						**≤8%**
Lot 2	Kit Control Low	118.1	1.60	1.4%	2.14	1.8%	0.65	0.6%	2.75	2.3%
	Kit Control High	297.7	3.90	1.3%	4.78	1.6%	3.00	1.0%	6.86	2.3%
	Sample 1	110.7	1.29	1.2%	1.79	1.6%	0.60	0.5%	2.28	2.1%
	Sample 2	203.0	3.26	1.6%	1.89	0.9%	4.10	2.0%	5.57	2.7%
	Sample 3	237.9	3.42	1.4%	3.57	1.5%	4.70	2.0%	6.83	2.9%
	Sample 4	305.9	3.07	1.0%	4.84	1.6%	2.95	1.0%	6.44	2.1%
Lot 3	Kit Control Low	119.7	1.91	1.6%	1.51	1.3%	0.00	0.0%	2.43	2.0%
	Kit Control High	307.0	4.43	1.4%	5.41	1.8%	0.95	0.3%	7.06	2.3%
	Sample 1	111.2	1.20	1.1%	1.79	1.6%	1.08	1.0%	2.41	2.2%
	Sample 2	208.3	2.83	1.4%	2.68	1.3%	2.22	1.1%	4.48	2.2%
	Sample 3	245.5	2.68	1.1%	4.04	1.6%	3.37	1.4%	5.90	2.4%
	Sample 4	317.1	4.78	1.5%	4.55	1.4%	1.12	0.4%	6.69	2.1%

* Total Precision includes within-run, between-run, and between-day variance components

Analytical Sensitivity

The estimations of the Limit of Blank (LoB), Limit of Detection (LoD) and Limit of Quantitation (LoQ) were performed according to CLSI EP17-A2. The LoB was 0.40 nmol/min/mL, LoD of the assay was estimated to be 0.74 nmol/min/mL and the LoQ was 10 nmol/min/mL with an allowable CV of 20%.

Linearity

Linearity of the PLAC® Test for Lp-PLA$_2$ Activity was assessed on one Beckman Coulter (Olympus) AU400® Clinical Chemistry Analyzer according to CLSI EP6-A using 3 kit lots. Several dilution series were prepared from native plasma samples

with known high and low Lp-PLA$_2$ activity levels. In the range of 6 to 382 nmol/min/mL, linear regression of Lp-PLA$_2$ activity levels resulted in slopes ranging from 0.98 to 1.04, intercepts ranging from -0.4 to -0.03 nmol/min/mL and R^2 values ranging from 0.995 to 0.999. Linearity was demonstrated from 10 to 382 nmol/min/mL with a deviation from linearity of ≤10%.

The measuring range of the assay is determined to be 10 to 382 nmol/min/mL with the low end of the range based on the Limit of Quantitation

Recovery

Various amounts of a high Lp-PLA$_2$ activity level solution were added to an enzyme-free diluent to create seven activity levels. These spiked solutions were assayed with 3 lots of reagents and the Lp-PLA$_2$ activity levels were then compared to expected values resulting in slopes ranging from 0.99 to 1.10, Intercepts ranging from -2.9 to 4.2 nmol/min/mL and R2 ranging from 0.997 to 1.000.

Analytical Specificity

Endogenous Interferences

The endogenous substances were titrated into four (4) plasma samples with known levels of each endogenous substance and five (5) replicates were tested for each level in a protocol developed according to CLSI EP7-A2. The following common substances, when added to plasma with Lp-PLA$_2$ activity levels ranging from 85 to 315 nmol/min/mL, met acceptance criteria 90-110% recovery in the measured Lp-PLA$_2$ activity level at the following levels:

Table 3 – Endogenous Interfering Substances and Test Concentrations

Potential Endogenous Interfering Substance	High Concentration Meeting Acceptance Criteria
Albumin	60 g/L
Conjugated Bilirubin	12 mg/dL
Unconjugated Bilirubin	20 mg/dL
Cholesterol	300 mg/dL
Triglycerides	400 mg/dL
Hemoglobin	1 mg/mL

Exogenous Substances

Exogenous substances (common and prescription drugs) were evaluated for interference in the assay following CLSI EP7-A2 guidelines. Four (4) native plasma samples ranging from 101 to 315 nmol/min/mL were spiked with two levels of each potential interferent and tested in duplicate. No appreciable interference was observed for the following substances at the spiked levels tested.

Table 4 – Exogenous Interfering Substances and Test Concentrations

Potential Exogenous Interfering Substance	Low Conc. (µmol/L)	High Conc. (µmol/L)
Acetaminophen	33	1324
Aspirin	720	3600
Atorvastatin	2	20
Diphenhydramine	2	20
Fenofibrate	42	125
Lisinopril	0.25	0.74
Niacin	480	4800
Tolbutamide	400	2300
Warfarin	10	33
Metformin	31	310
Clopidogrel bisulfate	10	100
Vitamin C	14	342

Specimen Handling and Stability

Specimen handling and stability was tested to assure accurate Lp-PLA$_2$ activity results using plasma, serum and unprocessed whole blood under specified conditions for the PLAC® Test for Lp-PLA$_2$ Activity on automated clinical chemistry analyzers.

The package insert states the following:

- Process blood using standard separation procedures.
  - Whole blood can be kept up to 4 hours at 20-22°C or up to 30 hours at 2-8°C prior to separation.

- Following centrifugation:
  - Examine for hemolysis. If present, discard sample and re-draw.
    - Sample can be tested immediately or stored prior to testing under the following conditions:
      - 24 hours at 20-26°C
      - Up to 2 weeks at 2-8°C
      - Up to 18 months at -20°C
      - Up to 2 years at -70°C
  - Plasma and serum samples can be freeze/thawed up to 5 times after freezing at either -70°C or -20°C.
  - When transporting samples, ship samples on cold packs at 2-8°C

Reagent Stability

Shelf Life (2-8ºC)

Real-Time Stability testing demonstrates a 13-month shelf life for the PLAC® Test for Lp-PLA$_2$ Activity kits. The labeled shelf life for each reagent when stored according to the listed conditions will be 12-months at 2-8ºC.

Open Vial Stability (2-8ºC)

Open vial stability testing was established at 16-weeks. The package insert states that opened reagents will be stable for 4-weeks when stored at 2-8ºC. The package insert states that opened calibrators and controls will be stable for 3 months when stored at 2-8 ºC.

On-Board Reagent Stability 2-8ºC

On-board Reagent Stability testing was established at 6-weeks. The package insert states that reagents stored on-board will be stable for 4-weeks at 2-8ºC.

Matrix Comparison

A specimen matrix comparison study was performed using five (5) different blood collection tube matrices with one (1) reagent lot to evaluate suitability with the PLAC® Test for Lp-PLA$_2$ Activity on one Beckman Coulter (Olympus) AU400® Clinical Chemistry Analyzer. The Lp-PLA$_2$ activity values of the samples ranged from 56 to 357 nmol/min/mL and were tested in singlicate and compared to K_2 EDTA plasma.

All tube types (K_3 EDTA plasma without separator gel, K_2 EDTA plasma and serum with and without separator gel) were comparable to K_2 EDTA plasma tube without separator gel.

10. Summary of Clinical Testing as Basis for Substantial Equivalence

Three aspects of Lp-PLA$_2$ Activity were evaluated to establish the clinical performance of the assay: 1) Clinical validation in the intended use population; 2) Analysis of Lp-PLA$_2$ Activity values in different ethnic groups; and 3) Clinical utility including benefit/risk of results. The clinical data provides evidence that the PLAC® Test for Lp-PLA$_2$ Activity, used in conjunction with clinical evaluation and patient risk assessment, is an aid in predicting risk of coronary heart disease (CHD) in patients with no prior history of cardiovascular events. Clinical performance of the PLAC® Test for Lp-PLA$_2$ Activity was successfully conducted meeting design input requirements and the intended use, and demonstrates that the assay system functions according to design specifications with both plasma and serum on automated clinical chemistry analyzers.

11. Conclusions Drawn from Non-clinical and Clinical Tests

Based on the information provided in this 510(k), the PLAC® Test for Lp-PLA$_2$ Activity is substantially equivalent to the predicate device. The clinical and non-clinical studies demonstrate that the proposed device is as safe, as effective and performs as well as the predicate device per 807.92(b)(3).