



SPECIAL 510(k) SUBSTANTIAL EQUIVALENCE DETERMINATION DECISION SUMMARY

I Background Information:

A 510(k) Number

K203136

B Applicant

Diazyme Laboratories Inc.

C Proprietary and Established Names

Diazyme PLAC® Test for Lp-PLA2 Activity

D Regulatory Information

Product Code(s)	Classification	Regulation Section	Panel
NOE	Class II	21 CFR 866.5600 - Low-Density Lipoprotein Immunological Test System	IM - Immunology

II Review Summary:

This 510(k) submission contains information/data on modifications made to the submitter's own CLASS II device requiring 510(k). The following items are present and acceptable.

1. The name and 510(k) number of the SUBMITTER'S previously cleared device. (For a preamendments device, a statement to this effect has been provided.) The PLAC Test for Lp-PLA2 Activity, K141575.
2. Submitter's statement that the **INDICATIONS FOR USE/INTENDED USE** of the modified device as described in its labeling **HAS NOT CHANGED** along with the proposed labeling which includes instructions for use, package labeling, and, if available, advertisements or promotional materials (labeling changes are permitted as long as they do not affect the intended use).

3. A description of the device **MODIFICATION(S)**, including clearly labeled diagrams, engineering drawings, photographs, user's and/or service manuals in sufficient detail to demonstrate that the **FUNDAMENTAL SCIENTIFIC TECHNOLOGY** of the modified device **has not changed. This change was for:**
 - The device calibration was changed so that the modified device is calibrated using calibration material that is supplied lyophilized and requires reconstitution prior to use.
 - Change in the name of the device from PLAC Test For Lp-pla2 Activity to Diazyme PLAC Test For Lp-pla2 Activity.
4. Comparison Information (i.e., similarities and differences) to the submitter's legally marketed predicate device including, labeling, intended use, and physical characteristics.
5. A Design Control Activities Summary which includes:
 - a) Identification of Risk Analysis method(s) used to assess the impact of the modification on the device and its components, and the results of the analysis.
 - b) Based on the Risk Analysis, an identification of the verification and/or validation activities required, including methods or tests used (analytical sensitivity [limit of blank, limit of detection, limit of quantitation], linearity, and method comparison studies) and acceptance criteria to be applied.

The labeling for this modified subject device has been reviewed to verify that the indication/intended use for the device is unaffected by the modification. In addition, the submitter's description of the particular modification(s) and the comparative information between the modified and unmodified devices demonstrate that the fundamental scientific technology has not changed. The submitter has provided the design control information as specified in The New 510(k) Paradigm and on this basis, I recommend the device be determined substantially equivalent to the previously cleared (or their preamendment) device.