K131821

510(k) Summary of Safety and Effectiveness

DEC 2 3 2013

This summary of safety and effectiveness information is being submitted in accordance with the requirements of The Safety Medical Devices Act of 1990 (SMDA 1990) and 21 CFR Part 807.92.

Assigned 510(k) Number:

Date of Summary Preparation: September 9, 2013

Manufacturer:

Phadia AB
Rapsgatan 7P
P.O. Box 6460
751 37 Uppsala, Sweden

510 (k) Contact Person:

Martin Mann
Regulatory Affairs Manager
Phadia US Inc.
4169 Commercial Avenue
Portage, Mi 49002, USA
+1 (-269-492) -1957 (Phone)
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Device Name: EliA™ Cardiolipin IgA Immunoassay

Common Name: Cardiolipin autoantibody immunological test system

Classification

Product Name	Product Code	Class	CFR
EliA™ Cardiolipin IgA	MID	II	866.5660

Substantial Equivalence to

Quanta Lite IgA ACA (HRP) K953366

Intended Use Statements of the New Device

EliA Cardiolipin IgA is intended for the in vitro semi-quantitative measurement of IgA antibodies directed to cardiolipin in human serum and plasma (heparin, EDTA, citrate) to aid in the diagnosis of antiphospholipid syndrome (APS) as well as thrombotic disorders related to systemic lupus erythematosus (SLE) in conjunction with other laboratory and clinical findings. EliA Cardiolipin IgA uses the EliA IgA method on the instruments Phadia 100.

EliA Cardiolipin IgA is intended for the in vitro semi-quantitative measurement of IgA antibodies directed to cardiolipin in human serum and plasma (heparin, EDTA, citrate) to aid in the diagnosis of antiphospholipid syndrome (APS) as well as thrombotic disorders related to systemic lupus erythematosus (SLE) in conjunction with other laboratory and clinical findings. EliA Cardiolipin IgA uses the EliA IgA method on the instruments Phadia 250.

Special condition for use statement

The device is for prescription use only.

Special instrument requirements

Phadia® 100/Phadia® 250 are fully automated immunoassay analyzers, which include software for evaluation of test results.

General Description of the New Device

The new device belongs to a fully integrated and automated system for immunodiagnostic testing. It comprises a Fluorescence-Immunoassay test system using EliA single wells as the solid phase and is intended to be performed on the instruments Phadia 100 and Phadia 250.

The conjugate for the EliA IgA method is mouse anti-human IgA beta-galactosidase, which uses 4-Methylumbelliferyl-ßD-Galactoside as substrate.

The total IgA calibration is based on a set of six WHO-standardized IgA Calibrators derived from human serum. They are used to establish an initial calibration curve, which may be used for up to 28 days on additional assays and can be stored by the instrument. Each additional assay includes calibrator (curve) controls that have to recover in defined ranges to ensure that the stored calibration curve is still valid. The Fluorescence-Immunoassay test system includes test-, method-specific and general reagents that are packaged as separate units.

Test Principle of the New Device
The EliA Wells are coated with the following antigen:

Test	Antigen coated to the wells:
EliA Cardiolipin IgA Well	Bovine cardiolipin antigen and bovine β2-glycoprotein I as co-factor

If present in the patient's specimen, antibodies to the antigens mentioned above bind to their specific antigen. After washing away non-bound antibodies, enzyme-labeled antibodies against human IgA antibodies (EliA IgA Conjugate) are added to form an antibody-conjugate complex. After incubation, non-bound conjugate is washed away and the bound complex is incubated with a Development Solution. After stopping the reaction, the fluorescence in the reaction mixture is measured. The higher the response value, the higher the amount of antibody bound and detected in the sample tested. To evaluate test results, the response for patient samples is compared directly to the response for calibrators.

Device Comparison
The new and the predicate device both represent non-competitive solid phase ELISAs. Both IVDs are used as an aid in the diagnosis of antiphospholipid syndrome (APS) as well as thrombotic disorders related to systemic lupus erythematosus (SLE).

Laboratory equivalence
The comparability of predicate device and new device is supported by a data set including

- **results obtained within a comparison study between new and predicate device**
- **results obtained for clinically defined sera**
- **results obtained for samples from apparently healthy subjects (normal population).**

In summary, all available data support that the new device is substantially equivalent to the predicate device.

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

PHADIA US, INC.
C/O MR. MARTIN ROBERT MANN
SENIOR REGULATORY AFFAIRS MANAGER
4169 COMMERCIAL AVENUE
PORTAGE, MI, 49002

December 23, 2013

Re: K131821
Trade/Device Name: EliA™ Cardiolipin IgA Immunoassay
EliA™ APS Positive Control 100
EliA™ APS Positive Control 250
EliA™ APS IgG/IgM/IgA Negative Control 100
EliA™ APS IgG/IgM/IgA Negative Control 250

Regulation Number: CFR §866.5660
Regulation Name: Multiple autoantibodies immunological test system
Regulatory Class: II
Product Code: MID, JJY
Dated: November 20, 2013
Received: November 21, 2013

Dear Mr. Mann:

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 Small Manufacturers, International and Consumer Assistance 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" (21CFR 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 Small Manufacturers, International and Consumer Assistance 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,

Maria M. Chan -S

Maria M. Chan, Ph.D.
Director
Division of Immunology and Hematology 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: December 31, 2013
See PRA Statement on last page.

510(k) Number *(if known)*
k131821

Device Name
EliA™ Cardiolipin IgA

Indications for Use *(Describe)*
EliA Cardiolipin IgA is intended for the in vitro semi-quantitative measurement of IgA antibodies directed to cardiolipin in human serum and plasma (heparin, EDTA, citrate) to aid in the diagnosis of antiphospholipid syndrome (APS) as well as thrombotic disorders related to systemic lupus erythematosus (SLE) in conjunction with other laboratory and clinical findings. EliA Cardiolipin IgA uses the EliA IgA method on the instruments Phadia 100.

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

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 807 Subpart C)

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FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

Maria M. Chan -S

PSC Publishing Services (301) 443-6740 EF

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Food and Drug Administration

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

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 807 Subpart C)

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510(k) Number *(if known)*
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Device Name
EliA™ APS Positive Control 100

Indications for Use *(Describe)*
EliA APS Positive Control 100 is intended for laboratory use in monitoring the performance of in vitro measurement of antibodies to cardiolipin and ß2-Glycoprotein I with Phadia 100 using the EliA IgG, IgM or IgA method.

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

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 807 Subpart C)

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510(k) Number *(if known)*
k131821

Device Name
EliA™ APS Positive Control 250

Indications for Use *(Describe)*
EliA APS Positive Control 250 is intended for laboratory use in monitoring the performance of in vitro measurement of antibodies to cardiolipin and ß2-Glycoprotein I with Phadia 250 using the EliA IgG, IgM or IgA method.

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

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 807 Subpart C)

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Form Approved: OMB No. 0910-0120
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510(k) Number *(if known)*
k131821

Device Name
EliA™ IgG/IgM/IgA Negative Control 100

Indications for Use *(Describe)*
EliA IgG/IgM/IgA Negative Control 100 is intended for laboratory use in monitoring the performance of in vitro measurement of autoantibodies with Phadia 100 using the EliA IgG or IgM or IgA method.

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

☐ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 807 Subpart C)

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Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: December 31, 2013
See PRA Statement on last page.

510(k) Number *(if known)*
k131821

Device Name
EliA™ IgG/IgM/IgA Negative Control 250

Indications for Use *(Describe)*
EliA IgG/IgM/IgA Negative Control 250 is intended for laboratory use in monitoring the performance of in vitro measurement of autoantibodies with Phadia 250 using the EliA IgG or IgM or IgA method.

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

☐ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 807 Subpart C)

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