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K072393

9. 510(k) Summary of Safety and Effectiveness

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: k072393

Date of Summary Preparation: December 3, 2007

Manufacturer:

Phadia AB
Rapsgatan 7
SE-751 37 Uppsala, Sweden

510 (k) Contact Person:

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Regulatory Affairs Manager
Phadia US Inc.
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Portage, Mi 49002, USA
269-492-1957 (Phone)
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Device Name:

EliA™ dsDNA Immunoassay
EliA™ ANA Control

Common Name:

Anti-dsDNA antibodies immunological test system and Control

Classification

Product Name	Product Code	Class	CFR
EliA™ dsDNA Immunoassay	LRM	II	866.5100
EliA™ ANA Control	JJY	I	862.1660

Substantial Equivalence to

DPC anti-DNA — 510(k) number: K874873

Intended Use Statement of the New Device

EliA dsDNA is intended for the in vitro quantitative measurement of IgG antibodies directed to dsDNA in human serum and plasma (heparin, EDTA, citrate) as an aid in the clinical diagnosis of systemic lupus erythematosus (SLE) in conjunction with other laboratory and clinical findings. EliA dsDNA Immunoassay uses the EliA IgG method on the instrument ImmunoCAP 100 and ImmunoCAP 250.

EliA ANA Control is intended for laboratory use in monitoring the performance of in vitro measurement of antinuclear antibodies (ANA) with ImmunoCAP 100 or ImmunoCAP 250 using the EliA IgG method.

Special condition for use statement

The device is for prescription use only.

Special instrument requirements

ImmunoCAP 100/ImmunoCAP 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 ImmunoCAP 100 and ImmunoCAP 250. The conjugate for the EliA IgG method is mouse anti-human IgG beta-galactosidase, which uses 4-Methylumbelliferyl-ßD-Galactoside as substrate. The total IgG calibration is based on a set of six WHO-standardized IgG 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 dsDNA Wells are coated with double-stranded plasmid DNA. If present in the patient's specimen, antibodies to dsDNA bind to their specific antigen. After washing away non-bound antibodies, enzyme-labeled antibodies against human IgG antibodies (EliA IgG 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 more specific IgG is present in the specimen. 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 are used as an aid in the diagnosis of Systemic Lupus Erythematosus (SLE) in conjunction with other laboratory and clinical findings.

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
2098 Gaither Road
Rockville MD 20850

DEC 07 2007

Phadia US, Inc.
c/o Mr. Martin R. Mann
Regulatory Affairs Manager
4169 Commercial Ave
Portage, MI 49002

Re: k072393
Trade/Device Name: EliA™ dsDNA
Regulation Number: 21 CFR 866.5100
Regulation Name: Antinuclear autoantibody, antigen and control
Regulatory Class: Class II
Product Code: LSW, JJY
Dated: November 26, 2007
Received: November 27, 2007

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.

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 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 Part 801); 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) 276-0450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. 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 http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Robert L. Becker, Jr., M.D., Ph.D.
Director
Division of Immunology and Hematology Devices
Office of In Vitro Diagnostic Device Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number: K072393

Device Name: **EliA™ dsDNA**

Indications For Use:

EliA dsDNA is intended for the in vitro quantitative measurement of IgG antibodies directed to dsDNA in human serum and plasma (heparin, EDTA, citrate) as an aid in the clinical diagnosis of systemic lupus erythematosus (SLE) in conjunction with other laboratory and clinical findings. EliA dsDNA uses the EliA IgG method on the instrument ImmunoCAP 100 and ImmunoCAP 250.

Prescription Use __√__ **AND/OR** **Over-The-Counter Use** _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

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Division Sign-Off

Concurrence of CDRH, Office of Device Evaluation (ODE)

Office of In Vitro Diagnostic
Device Evaluation and Safety

510(k) K072393

Indications for Use

510(k) Number: K072393

Device Name: **EliA™ ANA Control**

Indications For Use:

EliA ANA Control is intended for laboratory use in monitoring the performance of in vitro measurement of antinuclear antibodies (ANA) with ImmunoCAP 100 or ImmunoCAP 250 using the EliA IgG method.

Prescription Use __√___ **AND/OR** **Over-The-Counter Use** _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

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Concurrence of CDRH, Office of Device Evaluation (ODE)
Division Sign-Off

Office of In Vitro Diagnostic
Device Evaluation and Safety