K102673

SEP 30 2011

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:

Date of Summary Preparation: July 30, 2010

Manufacturer:
Phadia AB
Rapsgatan 7
SE-751 37 Uppsala, Sweden

510 (k) Contact Person:
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Device Name:
EliA™ RF IgM Immunoassay
EliA™ RF IgA Immunoassay
EliA™ RF Positive Control 100
EliA™ RF Positive Control 250

Common Name: Rheumatoid factor immunological test system

Classification

Product Name	Product Code	Class	CFR
EliA™ RF IgM	DHR	II	866.5775
EliA™ RF IgA	DHR	II	866.5775
EliA™ RF Positive Control	JJY	I	862.1660

Substantial Equivalence to

Quanta Lite Rf IgM Elisa	K971614
Quanta Lite Rf IgA Elisa	K983084

Intended Use Statements of the New Devices

1) EliA RF IgM is intended for the in vitro quantitative measurement of IgM class rheumatoid factor antibodies in human serum and plasma (Li-heparin, EDTA, citrate) to aid in the diagnosis of rheumatoid arthritis in conjunction with other laboratory and clinical findings. EliA RF IgM uses the EliA IgM method on the instruments Phadia 100 and Phadia 250.

2) EliA RF IgA is intended for the in vitro quantitative measurement of IgA class rheumatoid factor antibodies in human serum and plasma (Li-heparin, EDTA, citrate) to aid in the diagnosis of rheumatoid arthritis in conjunction with other laboratory and clinical findings.
EliA RF IgA uses the EliA IgA method on the instruments Phadia 100 and Phadia 250.

3) EliA RF Positive Control 100 is intended for laboratory use in monitoring the performance of in vitro measurement of rheumatoid factor (RF) with Phadia 100 using the EliA IgM or IgA method.

4) EliA RF Positive Control 250 is intended for laboratory use in monitoring the performance of in vitro measurement of rheumatoid factor (RF) with Phadia 250 using the EliA IgM or IgA method.

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 Devices

The new devices belong 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 IgM method is mouse anti-human IgM beta-galactosidase, which uses 4-Methylumbelliferyl-ßD-Galactoside as substrate.

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

The total IgM and IgA calibration is based on a set of six WHO-standardized IgM and IgA Calibrators, respectively, 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 Devices

The EliA Wells are coated with the following antigens:

Test	Antigen coated to the wells:
EliA RF IgM	Aggregated rabbit IgG
EliA RF IgA	Aggregated rabbit IgG

If present in the patient's specimen, rheumatoid factor binds to the antigen. After washing away non-bound antibodies, enzyme-labeled antibodies against human IgM or IgA antibodies (EliA IgM or 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 more specific IgM or IgA 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 devices both represent non-competitive solid phase ELISAs. Both IVDs are used as an aid in the diagnosis of rheumatoid arthritis.

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 devices are substantially equivalent to the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993

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

SEP 30 2011

Re: k102673
Trade/Device Name: EliA™ RF IgM Immunoassay
EliA™ RF IgA Immunoassay
EliA™ RF Positive Control 100
EliA™ RF Positive Control 250
Regulation Number: 21 CFR §866.5775
Regulation Name: Rheumatoid factor immunological test system
Regulatory Class: Class II (assay)
Product Codes: DHR, JJY
Dated: August 29, 2011
Received: August 30, 2011

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 class II (Special Controls), 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); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); 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 advice for your device on our labeling regulation (21 CFR Parts 801 and 809), please contact the Office of *In Vitro* Diagnostic Device Evaluation and Safety at (301) 796-5450. 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 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/cdrh/industry/support/index.html.

Sincerely yours,

Reena Philip

for Maria M. Chan, 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

Indication for Use

510(k) Number: k102673

Device Name: **EliA™ RF IgM**

Indication For Use:

EliA RF IgM is intended for the in vitro semi-quantitative measurement of IgM class rheumatoid factor antibodies in human serum and plasma (Li-heparin, EDTA, citrate) to aid in the diagnosis of rheumatoid arthritis in conjunction with other laboratory and clinical findings. EliA RF IgM uses the EliA IgM method on the instruments Phadia 100 and Phadia 250.

Prescription Use __√___ (21 CFR Part 801 Subpart D) And/Or Over the Counter Use ____. (21 CFR Part 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE; CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Device Evaluation and Safety (OIVD)

Division Sign-Off
Office of In Vitro Diagnostic Device
Evaluation and Safety

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Indication for Use

510(k) Number: k102673

Device Name: **EliA™ RF IgA**

Indication For Use:

EliA RF IgA is intended for the in vitro semi-quantitative measurement of IgA class rheumatoid factor antibodies in human serum and plasma (Li-heparin, EDTA, citrate) to aid in the diagnosis of rheumatoid arthritis in conjunction with other laboratory and clinical findings. EliA RF IgA uses the EliA IgA method on the instruments Phadia 100 and Phadia 250.

Prescription Use __√___ And/Or Over the Counter Use ____.
(21 CFR Part 801 Subpart D) (21 CFR Part 801 Subpart C)

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Indication for Use

510(k) Number (if known): K102673

Device Name: **EliA™ RF Positive Control 100**

Indication For Use:

EliA RF Positive Control 100 is intended for laboratory use in monitoring the performance of in vitro measurement of rheumatoid factor (RF) with Phadia 100 using the EliA IgM or IgA method.

Prescription Use __√____ And/Or Over the Counter Use ____.
(21 CFR Part 801 Subpart D) (21 CFR Part 801 Subpart C)

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Indication for Use

510(k) Number (if known): K102673

Device Name: **EliA™ RF Positive Control 250**

Indication For Use:

EliA RF Positive Control 250 is intended for laboratory use in monitoring the performance of in vitro measurement of rheumatoid factor (RF) with Phadia 250 using the EliA IgM or IgA method.

Prescription Use __√____ (21 CFR Part 801 Subpart D) And/Or Over the Counter Use ____. (21 CFR Part 801 Subpart C)

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