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:

AUG 18 2010

K093459

Date of Summary Preparation: August 2, 2010

Manufacturer:

Phadia AB
Rapsgatan 7
SE-751 37 Uppsala, Sweden

510 (k) Contact Person:

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Device Name:

EliA™ Gliadin^{DP} IgG Immunoassay
EliA™ Gliadin^{DP} IgA Immunoassay

Common Name:

Antibodies, Gliadin

Classification

Product Name	Product Code	Class	CFR
EliA™ Gliadin^{DP} IgG	MST	II	866.5750
EliA™ Gliadin^{DP} IgA	MST	II	866.5750

Substantial Equivalence to

INOVA Quanta Lite Gliadin IgA II	K052143
INOVA Quanta Lite Gliadin IgG II	K052142

Intended Use Statements of the New Devices

1) EliA™ Gliadin^{DP} IgG is intended for the in vitro semi-quantitative measurement of IgG antibodies directed to gliadin in serum and plasma (heparin, EDTA, citrate) to aid in the diagnosis of celiac disease in conjunction with other laboratory and clinical findings. EliA™ Gliadin^{DP} IgG uses the EliA IgG method on the instruments Phadia® 100 and Phadia® 250.

2) EliA™ Gliadin^{DP} IgA is intended for the in vitro semi-quantitative measurement of IgA antibodies directed to gliadin in serum and plasma (heparin, EDTA, citrate) to aid in the diagnosis of celiac disease in conjunction with other laboratory and clinical findings. EliA™ Gliadin^{DP} IgA uses the EliA IgA method on the instruments Phadia® 100 and 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 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 IgG method is mouse anti-human IgG 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 IgG and IgA calibration is based on a set of six WHO-standardized IgG 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 antigen:

Test	**Antigen coated to the wells:**
EliA Gliadin^{DP} IgG/IgA	Synthetic deamidated gliadin peptides

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 IgG or IgA antibodies (EliA IgG 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 IgG 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 celiac disease.

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

Food and Drug Administration
10903 New Hampshire Avenue
Document Mail Center – WO66-0609
Silver Spring, MD 20993-0002

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

AUG 13 2010

Re: k093459
Trade/Device Name: EliA™ Gliadin^{DP} IgG Immunoassay
EliA™ Gliadin^{DP} IgA Immunoassay
EliA™ Celiac Positive Control 100
EliA™ Celiac Positive Control 250
EliA™ IgG/IgM/IgA Negative Control 100
EliA™ IgG/IgM/IgA Negative Control 250
Regulation Number: 21 CFR 866.5750
Regulation Name: Radioallergosorbent (RAST) immunological test system
Regulatory Class: Class II
Product Code: MST, JJY
Dated: August 10, 2010
Received: August 11, 2010

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

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,

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

AUG 1 3 2010

510(k) Number (if known): K093459

Device Name: **EliA™ Gliadin^{DP} IgG**

Indication For Use:

EliA™ Gliadin^{DP} IgG is intended for the in vitro semi-quantitative measurement of IgG antibodies directed to gliadin in human serum and plasma (heparin, EDTA, citrate) to aid in the diagnosis of celiac disease in conjunction with other laboratory and clinical findings. EliA™ Gliadin^{DP} IgG uses the EliA IgG 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)

(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)

Maria M Chan

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

510(k) K093459

Indication for Use

510(k) Number (if known): K093459

Device Name: **EliA™ Gliadin^{DP} IgA**

AUG 13 2010

Indication For Use:

EliA™ Gliadin^{DP} IgA is intended for the in vitro semi-quantitative measurement of IgA antibodies directed to gliadin in human serum and plasma (heparin, EDTA, citrate) to aid in the diagnosis of celiac disease in conjunction with other laboratory and clinical findings. EliA™ Gliadin^{DP} IgA uses the EliA IgA 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)

Maria In Chan

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

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