MAR 14 2007

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: K063775

Date of Summary Preparation: December 20, 2006

Manufacturer:
Phadia AB
Rapsgatan 7
SE-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)
+1 (-269-492) -7541 (Fax)
martin.mann@phadia.com

Device Name:
EliA™ Gliadin IgA Assay
EliA™ Gliadin IgG Assay
EliA™ Celiac Control

Common Name: Antibodies, Gliadin

Classification

Product Name	Product Code	Class	CFR
EliA™ Gliadin IgA	MST	II	866.5750
EliA™ Gliadin IgG	MST	II	866.5750
EliA™ Celiac Control	JJY	I	862.1660

Substantial Equivalence to

Varelisa Gliadin IgA Antibodies	510(k) number: K041354
Varelisa Gliadin IgG Antibodies	510(k) number: K041357

Intended Use Statement of the New Device / EliA Gliadin IgA

EliA Gliadin IgA is intended for the in vitro semi-quantitative measurement of IgA antibodies directed to gliadin in serum or plasma to aid in the diagnosis of celiac disease in conjunction with other laboratory and clinical findings. EliA Gliadin IgA uses the EliA IgA method on the instrument ImmunoCAP 100 and ImmunoCAP 250.

EliA Celiac Control is intended for laboratory use in monitoring the performance of in vitro measurement of antibodies to tissue transglutaminase (tTG) and gliadin with ImmunoCAP 100 or 250 using the EliA IgG or IgA method.

Special condition for use statement

The device is for prescription use only.

Special instrument requirements

ImmunoCAP100/ImmunoCAP250 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 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 be measured in defined ranges to check whether 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 Gliadin IgA Wells are coated with gliadin antigen. If present in the patient's specimen, antibodies to gliadin bind to their specific antigen. After washing away non-bound antibodies, enzyme-labelled 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

more specific 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 device both represent non-competitive solid phase EIAs. Both IVDs are used as an aid in the diagnosis of Celiac Disease, 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.

Intended Use Statement of the New Device / EliA Gliadin IgG

EliA Gliadin IgG is intended for the in vitro semi-quantitative measurement of IgG antibodies directed to gliadin in serum or plasma to aid in the diagnosis of celiac disease, in conjunction with other laboratory and clinical findings. EliA Gliadin IgG uses the EliA IgG method on the instruments ImmunoCAP 100 and ImmunoCAP 250.

EliA Celiac Control is intended for laboratory use in monitoring the performance of in vitro measurement of antibodies to tissue transglutaminase (tTG) and gliadin with ImmunoCAP 100 or 250 using the EliA IgG or IgA method.

Special condition for use statement
The device is for prescription use only.

Special instrument requirements
ImmunoCAP100/ImmunoCAP250 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 be measured in defined ranges to check whether 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 Gliadin IgG Wells are coated with Gliadin Antigen. If present in the patient's specimen, antibodies to Gliadin bind to their specific antigen. After washing away non-bound antibodies, enzyme-labelled 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 represent non-competitive solid phase EIAs. Both IVDs are used as an aid in the diagnosis of Celiac Disease, 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

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

MAR 14 2007

Re: k063775
Trade/Device Name: EliA™ Gliadin IgA, EliA™ Gliadin IgG and EliA™ Celiac Control
Regulation Number: 21 CFR 866.5750
Regulation Name: Radioallergosorbent (RAST) immunological test system
Regulatory Class: Class II
Product Code: MST, JJY
Dated: February 12, 2007
Received: February 13, 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). 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: K063775

Device Name: **EliA™ Gliadin IgA**

Indications For Use:

EliA Gliadin IgA is intended for the in vitro semi-quantitative measurement of IgA antibodies directed to gliadin in serum or plasma to aid in the diagnosis of celiac disease in conjunction with other laboratory and clinical findings. EliA Gliadin IgA uses the EliA IgA 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)

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

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

Office of In Vitro Diagnostic
Device Evaluation and Safety

510(k) K063775

Indications for Use

510(k) Number: K063775

Device Name: **EliA™ Gliadin IgG**

Indications For Use:

EliA Gliadin IgG is intended for the in vitro semi-quantitative measurement of IgG antibodies directed to gliadin in serum or plasma to aid in the diagnosis of celiac disease in conjunction with other laboratory and clinical findings. EliA Gliadin IgG uses the EliA IgG method on the instruments ImmunoCAP 100 and ImmunoCAP 250.

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

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Division Sign-Off

Office of In Vitro Diagnostic
Device Evaluation and Safety

510(k) K063775

Indications for Use

510(k) Number: K063775

Device Name: **EliA™ Celiac Control**

Indications For Use:

EliA Celiac Control is intended for laboratory use in monitoring the performance of in vitro measurement of antibodies to gliadin with ImmunoCAP 100 or 250 using the EliA IgG or IgA method.

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

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

Division Sign-Off

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

510(k) K063775