K121463

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510(k) Summary

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.

Premarket Notification 510(k) No:

Date of Summary Preparation: May 16, 2012

Distributor:
Phadia US Inc.
4169 Commercial Avenue
Portage, MI 49002
269-492-1957

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

Company Contact Person:
Martin Mann
Regulatory Affairs Manager
Phadia US Inc.
4165 Commercial Avenue
Portage, MI 49002
269-492-1957

Device Name:
- ImmunoCAP Allergen k82, Latex (Art.No. 14-4511-01)

Common Name:
Automated in vitro quantitative assay for the measurement of allergen specific IgE antibodies.

Classification:

Product Name	ImmunoCAP Allergen
Product Code	DHB
Class	II
CFR	866.5750

Substantial Equivalence to:
- ImmunoCAP Allergen k82, Latex (Art. No. 14-4345-01), K972068

Indications For Use Statement

ImmunoCAP Specific IgE is an in vitro quantitative assay for the measurement of allergen specific IgE in human serum or plasma (EDTA or Na-Heparin). ImmunoCAP Specific IgE is to be used with instruments Phadia 100, Phadia 250, Phadia 1000, Phadia 2500 and Phadia 5000. It is intended for in vitro diagnostic use as an aid in the clinical diagnosis of IgE mediated allergic disorders in conjunction with other clinical findings, and is to be used in clinical laboratories.

Device Description

Reagents

ImmunoCAP Specific IgE reagents are modular in concept and are available individually. For a complete listing of reagents needed to perform the Phadia ImmunoCAP Specific IgE assay, please consult the ImmunoCAP Specific IgE Conjugate Directions for Use.

Instrument System

Phadia 100, Phadia 250, Phadia 1000, Phadia 2500 and Phadia 5000 instruments with built-in software process all steps of the assay and print results automatically after the assay is completed.

ImmunoCAP Specific IgE, Test Principle

The allergen of interest, covalently coupled to ImmunoCAP, reacts with the specific IgE in the patient sample. After washing away non-specific IgE, enzyme labeled antibodies against IgE are added to form a complex. After incubation, unbound enzyme-anti-IgE is washed away and the bound complex is then incubated with a developing agent. After stopping the reaction, the fluorescence of the eluate is measured. The higher the response value, the more specific IgE is present in the specimen. To evaluate the test results, the responses for the patient samples are transformed to concentrations with the use of a calibration curve.

Performance characteristics

The updated ImmunoCAP Allergen k82, Latex was verified in a comparison study to the currently cleared ImmunoCAP Allergen k82, Latex. Clinical positive samples, as well as samples from healthy, non-atopic donors were used in the study. The performance characteristics of the updated ImmunoCAP Allergen k82, Latex were established through studies of Precision, including Lot-to-Lot Reproducibility, Linearity and Limit of Detection. Inhibition studies verified the immunological specificity of the allergen.

Conclusion

The safety and effectiveness of the cleared ImmunoCAP Specific IgE system, intended for the determination of specific IgE antibodies, have been established in previous 510(k) submissions. The update of ImmunoCAP Allergen k82, Latex does not affect the Intended Use or in the Indications for Use statements. The data included in this 510(k) submission demonstrate that the updated ImmunoCAP Allergen k82, Latex is substantially equivalent to the current product.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-002

January 29, 2013

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

Re: k121463
Trade/Device Name: ImmunoCAP Allergen k82, Latex
Regulation Number: 21 CFR §866.5750
Regulation Name: Radioallergosorbent (RAST) Immunological Test System
Regulatory Class: Class II
Product Code: DHB
Dated: January 04, 2013
Received: January 07, 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

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 regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. 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 (OIR)
Center for Devices and Radiological Health

Indications for Use

510(k) Number (if known): K121463

Device Name: ImmunoCAP Specific IgE

Indications For Use:

ImmunoCAP Specific IgE is an *in vitro* quantitative assay for the measurement of allergen specific IgE in human serum or plasma (EDTA or Na-Heparin). ImmunoCAP Specific IgE is to be used with instruments Phadia 100, Phadia 250, Phadia 1000, Phadia 2500 and Phadia 5000. It is intended for *in vitro* diagnostic use as an aid in the clinical diagnosis of IgE mediated allergic disorders in conjunction with other clinical findings, and is to be used in clinical laboratories.

Prescription Use ____X___ 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 In Vitro Diagnostic Devices (OIVD)

Maria M Chan
Division Sign-Off

Office of In Vitro Diagnostics and Radiological Health

510(k) K121463