K122197

ThermoFisher
SCIENTIFIC

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: July 6, 2012

AUG 2 8 2013

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 Names:

- ImmunoCAP Allergen e101, Allergen Component rCan f 1, Dog
- ImmunoCAP Allergen e102, Allergen Component rCan f 2, Dog
- ImmunoCAP Allergen e221, Allergen component nCan f 3, Dog serum albumin
- ImmunoCAP Allergen e226, Allergen component rCan f 5, Dog
- ImmunoCAP Allergen f353, Allergen component rGly m 4 PR-10, Soy
- ImmunoCAP Allergen f431, Allergen component nGly m 5 Beta-conglycinin, Soy
- ImmunoCAP Allergen f432, Allergen component nGly m 6 Glycinin, Soy
- ImmunoCAP Allergen t224, Allergen component rOle e 1, Olive
- ImmunoCAP Allergen t227, Allergen component nOle e 7 LTP, Olive
- ImmunoCAP Allergen t240, Allergen component rOle e 9, Olive

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

Classification:

Product Name	ImmunoCAP Allergen Components
Product Code	DHB
Class	II
CFR	866.5750

Substantial Equivalence to:

ImmunoCAP Specific IgE	(k051218)
ImmunoCAP Allergens	(k962274)

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 associated software process all steps of the assay and calculate 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 new ImmunoCAP Allergen Components were compared with the extract based predicate devices with the use of clinical samples, as well as samples from healthy, non-atopic donors. The performance characteristics of the new ImmunoCAP Allergen Components were established through studies of Precision including Lot-to-Lot Reproducibility, Linearity and Limit of Detection. Inhibition studies verified the analytical specificity of the allergen components.

Conclusion

The safety and effectiveness of the cleared device ImmunoCAP Specific IgE system for the determination of specific IgE antibodies have been established in previous 510(k) submissions. This submission covers the addition of 10 new ImmunoCAP Allergen Components to the existing ImmunoCAP Specific IgE assay. The addition of the new ImmunoCAP Allergens does not affect the Intended Use / Indications for Use Statements.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

August 28, 2013

THERMOFISHER SCIENTIFIC
C/O MR. MARTIN R. MANN
SENIOR REGULATORY AFFAIRS MANAGER
IMMUNODIAGNOSTICS PHADIA US INC
4169 COMMERCIAL AVE
PORTAGE MI 49002

Re: K122197
Trade/Device Name: ImmunoCAP Allergen e101, Allergen Component rCan f 1, Dog
ImmunoCAP Allergen e102, Allergen Component rCan f 2, Dog
ImmunoCAP Allergen e221, Allergen Component nCan f 3, Dog serum albumin
ImmunoCAP Allergen e226, Allergen Component rCan f 5, Dog
ImmunoCAP Allergen f353, Allergen Component rGly m 4 PR10, Soy
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ImmunoCAP Allergen f432, Allergen Component nGly m 6 Glycinin, Soy
ImmunoCAP Allergen t224, Allergen Component rOle e1, Olive
ImmunoCAP Allergen t227, Allergen Component nOle e 7 LTP, Olive
ImmunoCAP Allergen t240, Allergen Component rOle e9, Olive
Regulation Number: 21 CFR 866.5750
Regulation Name: Radioallergosorbent (RAST) immunological test system
Regulatory Class: II
Product Code: DHB
Dated: August 13, 2013
Received: August 20, 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 CFR Part 807); labeling (21 CFR Parts 801 and 809); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set 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 regulations (21 CFR Parts 801 and 809), please contact 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. 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,

Reena Philip -S

for

Maria M. Chan, Ph.D.
Director, Division of Immunology and Hematology Devices
Office of In Vitro Diagnostics and Radiological Health
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number: k122197

Device Name: ImmunoCAP Specific IgE

Indications For Use:

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Prescription Use __X____ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (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 Diagnostics and Radiological Health (OIR)

Reena Philip -S

Division Sign-Off
Office of In Vitro Diagnostics and Radiological Health

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