



April 16, 2018

Phadia AB
% Martin Mann
Sr. Regulatory Affairs Manager
Phadia US Inc
4169 Commercial Ave
Portage, Michigan 49002

Re: K173726

Trade/Device Name: ImmunoCAP Specific IgE, ImmunoCAP Allergen f447, Allergen Component
rAra h 6, Peanut

Regulation Number: 21 CFR 866.5750

Regulation Name: Radioallergosorbent (RAST) immunological test system

Regulatory Class: Class II

Product Code: DHB

Dated: December 4, 2017

Received: December 5, 2017

Dear Martin 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 Part

801 and Part 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.

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.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (<https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/>) and CDRH Learn (<http://www.fda.gov/Training/CDRHLearn>). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (<http://www.fda.gov/DICE>) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,


Kelly Oliner -S

For
Lea Carrington
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 (if known)

K173726

Device Name

ImmunoCAP Specific IgE

ImmunoCAP Allergen f447, Allergen Component rAra h 6, Peanut

Indications for Use (Describe)

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.

Type of Use (Select one or both, as applicable)

Prescription Use (Part 21 CFR 801 Subpart D)

Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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510(k) Summary

This 510(k) Summary is prepared in accordance with the requirements of 21 CFR Part 807.92.

Premarket Notification 510(k) No:

Date of Summary Preparation: December 4, 2017

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

Distributor: Phadia US Inc.
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Device Name:

ImmunoCAP Specific IgE

- ImmunoCAP Allergen f447, Allergen Component rAra h 6, Peanut

Common Name:

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

Classification:

<u>Product Code</u>	DHB
<u>Class</u>	II
<u>CFR</u>	866.5750

Substantial Equivalence to: k051218, k962274

ImmunoCAP Specific IgE

- ImmunoCAP Allergen f13, Peanut (14-4126-01)

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.

Reason for Submission

This submission is an addition of a new ImmunoCAP Allergen Component to the previously cleared and well established ImmunoCAP Allergen Specific IgE assay system. The addition of the new ImmunoCAP Allergen Component does not affect the Intended Use or the Indications for Use Statements.

The previously cleared system may be referenced under k051218.

Performance Characteristics

The new ImmunoCAP Allergen Component was compared with the extract based predicate device with the use of clinical samples, as well as samples from healthy, non-atopic donors. The performance characteristics of the new ImmunoCAP Allergen Component was established through verification studies of Precision, Lot-to-Lot Reproducibility, Linearity, Limit of Detection, and Stability. Inhibition studies verified the analytical specificity of the allergen component.

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 a new ImmunoCAP Allergen Component to the existing ImmunoCAP Specific IgE assay. The addition of the new ImmunoCAP Allergen Component does not affect the Intended Use / Indications for Use Statements.