May 15, 2019

Phadia AB
Sheryl Skinner
Associate Director Regulatory and Quality
Phadia US Inc
4169 Commercial Ave
Portage, Michigan 49002

Re: K190315
Trade/Device Name: ImmunoCAP Allergen e229, Allergen Component rCan f 4 Dog, ImmunoCAP Allergen e230, Allergen Component rCan f 6 Dog, ImmunoCAP Allergen e231, Allergen Component rFel d 7 Cat
Regulation Number: 21 CFR 866.5750
Regulation Name: Radioallergosorbent (RAST) immunological test system
Regulatory Class: Class II
Product Code: DHB
Dated: February 12, 2019
Received: February 13, 2019

Dear Sheryl Skinner:

This letter corrects our substantially equivalent letter of May 14, 2019.

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. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. 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) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; 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 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,

Douglas A. Jeffery -S

Doug Jeffery
Acting Deputy Director
Division of Immunology and Hematology Devices
OHT7: Office of In Vitro Diagnostics
and Radiological Health
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
k190315

Device Name
ImmunoCAP Specific IgE
ImmunoCAP Allergen e229, Allergen Component rCan f 4 Dog, ImmunoCAP Allergen e230, Allergen Component rCan f 6 Dog, ImmunoCAP Allergen e231, Allergen Component rFel d 7 Cat

Indications for Use *(Describe)*
ImmunoCAP Specific IgE Assay is an in vitro quantitative assay for the measurement of allergen specific IgE in human serum or plasma (EDTA or Na-Heparin). 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. ImmunoCAP Specific IgE is to be used with the instrument Phadia 100, Phadia 250, Phadia 1000, Phadia 2500 and Phadia 5000.

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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

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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: K190315

Date of Summary Preparation: February 11, 2019

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

Distributor:
Phadia US Inc.
4169 Commercial Avenue
Portage, MI 49002

Company Contact Person:
Sheryl Skinner
Associate Director Quality and Regulatory
Phadia US Inc.
4169 Commercial Avenue
(269) 568-3603
sheryl.skinner@thermofisher.com

Device Name:
ImmunoCAP Specific IgE

- ImmunoCAP Allergen e229, Allergen Component rCan f4, Dog (14-5755-01)
- ImmunoCAP Allergen e230, Allergen Component rCan f6, Dog (14-6081-01)
- ImmunoCAP Allergen e231, Allergen Component rFel d7, Cat (14-6082-01)

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

Classification:

Product Code	DHB
Class	II
CFR	866.5750

Substantial Equivalence to: K051218, K962274
ImmunoCAP Specific IgE

- ImmunoCAP Allergen e5, Dog dander (14-4110-01)
- ImmunoCAP Allergen e1, Cat dander (14-4109-01)

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). 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. ImmunoCAP Specific IgE is to be used with the instruments Phadia 100, Phadia 250, Phadia 1000, Phadia 2500, and Phadia 5000.

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 instrument systems, and associated software, processes all steps of the assay and calculates 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 to add three new ImmunoCAP Allergen Components to the previously cleared ImmunoCAP Allergen Specific IgE assay system.

The addition of the new ImmunoCAP Allergen Components do 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 Components were compared to the extract based predicate device with the use of clinical positive samples. In addition, samples from healthy, non-atopic donors were studied. Analytical performance characteristics for the new ImmunoCAP Allergen Components were established by Precision, Lot-to-Lot Reproducibility, Linearity, Limit of Detection, and Stability studies. 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 three new ImmunoCAP Allergen Component to the existing ImmunoCAP Specific IgE assay. The addition of the new ImmunoCAP Allergen Components do not affect the Intended Use / Indications for Use Statements.