May 1, 2020

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

Re: K200279
Trade/Device Name: ImmunoCAP Allergen o215, Component nGal-alpha-1,3-Gal(alpha-Gal) Thyroglobulin, bovine
Regulation Number: 21 CFR 866.5750
Regulation Name: Radioallergosorbent (Rast) Immunological Test System
Regulatory Class: Class II
Product Code: DHB
Dated: January 31, 2020
Received: February 4, 2020

Dear Sheryl Skinner:

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/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); 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 https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). 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 (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Carolina Kagan
Acting Chief
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)*
K200279

Device Name
ImmunoCAP Allergen o215, Component nGal-alpha-1,3-Gal (alpha-Gal) Thyroglobulin, bovine

Indications for Use *(Describe)*
ImmunoCAP Allergen o215, Component nGal-alpha-1,3-Gal (alpha-Gal) Thyroglobulin, bovine, is intended for in vitro diagnostic use, in human serum or EDTA plasma, as an aid in the diagnosis of IgE mediated mammalian (red) meat hypersensitivity, due to alpha-Gal sensitization, and to be used in conjunction with other clinical findings. This test is not to be the sole criterion for diagnosing allergy to alpha-Gal. It is a quantitative test to be used in clinical laboratories. ImmunoCAP Allergen o215, alpha-Gal is to be used with the ImmunoCAP Specific IgE assay on the instrument Phadia™ 250.

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.

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510(k) Decision Summary

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

Premarket Notification 510(k) No: K200279

Date of Summary Preparation: April 30, 2020

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.
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Device Name:
ImmunoCAP Specific IgE
- ImmunoCAP Allergen o215, Component nGal-alpha-1,3-Gal (alpha-Gal) Thyroglobulin, bovine (14-5997-02)

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

Classification:

Product Code	DHB
Class	II
CFR	866.5750 - Radioallergosorbent (RAST) immunological test system

Substantial Equivalence to: K051218, ImmunoCAP Specific IgE

Indications For Use Statement
ImmunoCAP Allergen o215, Component nGal-alpha-1,3-Gal (alpha-Gal) Thyroglobulin, bovine, is intended for in vitro diagnostic use, in human serum or EDTA plasma, as an aid in the diagnosis of IgE mediated mammalian (red) meat hypersensitivity, due to alpha-Gal sensitization, and to be used in conjunction with other clinical findings. This test is not to be the sole criterion for diagnosing allergy to alpha-Gal. It is a quantitative test to be used in clinical laboratories.

ImmunoCAP Allergen o215, alpha-Gal is to be used with the ImmunoCAP Specific IgE assay on the instrument Phadia™ 250.

Device Description
Reagents
ImmunoCAP Allergen o215, Component nGal-alpha-1,3-Gal (alpha-Gal) Thyroglobulin, bovine, is a component of, and is designed to be used with, the ImmunoCAP Specific IgE assay, previously cleared under K051218. The test has the same overall design as all other ImmunoCAP Allergen components and uses identical assay and system specific reagents, instruments and software.

Instrument System
The ImmunoCAP Specific IgE assay runs on the Phadia Instrument Systems using the Phadia Information Data Manager (IDM) or Phadia Prime software. No modifications to any of the reagents, instruments or software have been made to enable the use of ImmunoCAP Allergen o215, alpha-Gal. Analytical and clinical validation of this assay was performed on Phadia 250.

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 for the clearance of the more specific, clinical, Intended Use of ImmunoCAP Allergen o215, alpha-Gal to be used together with the previously cleared ImmunoCAP Allergen Specific IgE assay system.

Performance Characteristics
Analytical performance characteristics for the new ImmunoCAP Allergen Components were established by studies of Precision, Lot-to-Lot Reproducibility, Linearity, Limit of Quantitation, Sample Matrix equivalency, Interference, Inhibition and Stability. Clinical performance was evaluated in a retrospective study including samples from 200 subjects with a case history of mammalian meat hypersensitivity and 110 control subjects.

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. The data in this submission supports that the new device ImmunoCAP Allergen o215, Component nGal-alpha-1,3-Gal (alpha-Gal) Thyroglobulin, bovine, is substantially equivalent to the predicate device.