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

PHADIA AB
Mr. Martin Mann
Senior Regulatory Affairs Manager
4169 Commercial Ave.
Portage, MI 49002

May 10, 2017

Re: K163370
Trade/Device Name: ImmunoCAP Allergen W1, Common Ragweed;
ImmunoCAP Specific IgE
Regulation Number: 21 CFR 866.5750
Regulation Name: Radioallergosorbent (RAST) immunological test system
Regulatory Class: II
Product Code: DHB
Dated: February 27, 2017
Received: February 28, 2017

Dear Mr. Mann:

This letter corrects our substantially equivalent letter of May 5, 2017.

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 Industry and Consumer Education 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" (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.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education 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,

Sic Lung Chan -S

For:
Leonthena Carrington, MBA, MS, MT (ASCP)
Division Director
Division of Immunology and Hematology Devices
Office of *In Vitro* Diagnostics
and Radiological Health
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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
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Device Name
ImmunoCAP Specific IgE
ImmunoCAP Allergen w1, Common ragweed

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 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: k163370

Date of Summary Preparation: February 15, 2017

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

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

Company contact person:
Martin Mann
Regulatory Affairs Manager
Phadia US Inc.
269-204-7049
martin.mann@thermofisher.com

Device Name:
ImmunoCAP Specific IgE
- ImmunoCAP Allergen w1, Common ragweed (14-4531-01)

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: k962274, k051218
ImmunoCAP Specific IgE
- ImmunoCAP Allergen w1, Common ragweed (14-4162-01)

Indications For Use/Intended 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

Assay reagents

ImmunoCAP Allergen w1, Common ragweed, is part of ImmunoCAP Specific IgE assay system. ImmunoCAP Specific IgE reagents are modular in concept and are available individually. For a complete listing of reagents needed to perform 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.

Description of change

The current submission describes a change of this allergen reagent due to naturally increased amounts of the major allergen component Amb a 1 in ragweed pollen.

No changes of Intended Use/Indications for Use or fundamental scientific technology of the assay system, or any other reagents of the system, instruments or software, have been made due to the update of ImmunoCAP Allergen w1, Common ragweed.

Performance characteristics

The new device, ImmunoCAP Allergen w1, Common ragweed (updated), was compared with the predicate device, ImmunoCAP Allergen w1, Common ragweed (current), with the use of clinical positive samples, as well as samples from healthy, non-atopic donors. The performance characteristics of the updated ImmunoCAP Allergen w1 were established through verification studies of precision, lot-to-lot reproducibility, limit of detection/limit of quantitation and linearity. Inhibition studies verified the analytical specificity of the updated ImmunoCAP Allergen w1.

The obtained concentrations of specific IgE antibodies in w1 positive samples are increased approximately two times with the updated ImmunoCAP Allergen w1, compared to the current ImmunoCAP Allergen w1.
The negative samples with the current ImmunoCAP Allergen w1 remain negative with the updated ImmunoCAP Allergen w1, with no change of background level. Furthermore, the LoQ for the updated product remain unchanged.
It is expected that some samples not detected (those just below 0.1 kU_A/l) with the current product will become analytically positive due to the general increase of specific IgE concentration levels of the updated product. However, since such very low samples are rare, this should have little impact on the clinical performance of the product in a general population of w1 allergic patients.

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 w1, Common ragweed, does not affect the Intended Use or the Indications for Use statements or the fundamental scientific technology of the assay. The verification studies performed demonstrate that the updated ImmunoCAP Allergen w1, Common ragweed is substantially equivalent to the currently cleared product. The general increase in measured specific IgE levels in sensitized patients is due to a better performing product containing higher amounts of the major allergen component Amb a 1 in ragweed pollen extract.