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
MARTIN MANN
REGULATORY AFFAIRS MANAGER
4169 COMMERCIAL AVENUE
PORTAGE, MI 49002

July 28, 2016

Re: K161889
Trade/Device Name: ImmunoCAP Specific IgE Assay and ImmunoCAP Total IgE Assay
Regulation Number: 21 CFR 866.5750
Regulation Name: Radioallergosorbent (RAST) immunological test system
Regulatory Class: Class II
Product Code DHB, DGC
Dated: July 8, 2016
Received: July 11, 2016

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 regulation (21 CFR Part 801), 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" (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 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,

Kelly Oliner -S

For,
Leonthena Carrington, MS, MBA, MT(ASCP)
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)*
-

Device Name
ImmunoCAP Specific IgE

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.

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.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

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)*
-

Device Name
ImmunoCAP Total IgE

Indications for Use *(Describe)*
ImmunoCAP Total IgE is an in vitro test system for the quantitative measurement of circulating total IgE in human serum and plasma. 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 Total IgE is to be used with the instruments Phadia 100, Phadia 250, Phadia 1000, Phadia 2500 or 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)

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510(k) Summary

This summary of safety and effectiveness information is being submitted in accordance with the requirements of 21 CFR Part 807.92.

Premarket Notification 510(k) No:

Date of Summary Preparation: July 7, 2016

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.
269-492-1957
martin.mann@thermofisher.com

Device Name (1):
ImmunoCAP Specific IgE

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
ImmunoCAP Specific IgE

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 Name (2):
ImmunoCAP Total IgE

Common name:
Automated in vitro quantitative assay for the measurement of Total IgE

Classification:

Product code	DGC
Class	II
CFR	866.5510

Substantial Equivalence to: k133404
ImmunoCAP Total IgE

Indications For Use / Intended Use Statement
ImmunoCAP Total IgE is an in vitro test system for the quantitative measurement of circulating total IgE in human serum and plasma. 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 Total IgE is to be used with the instruments Phadia 100, Phadia 250, Phadia 1000, Phadia 2500 or Phadia 5000.

Device Description

Assay reagents
The general ImmunoCAP reagents include ImmunoCAP Specific or Total IgE Conjugate, ImmunoCAP Specific or Total IgE Curve Control, ImmunoCAP Specific or Total IgE Calibrators, Specific or Total IgE anti-IgE, Allergen ImmunoCAP carriers (only for determination of Specific IgE), Development solution, Stop Solution and Washing Solution. The method specific reagents consist of individual purified allergen (native or recombinant), covalently coupled to a support in a plastic housing (only for determination of Specific IgE).

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.

ImmunoCAP Total IgE, Test Principle
Anti-IgE covalently coupled to ImmunoCAP, reacts with the total IgE in the patient sample. After washing, enzyme labeled antibodies against IgE are added to form a complex. Following

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 IgE is present in the sample. 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
Introduction of a new Reference Material for standardization of ImmunoCAP Specific and Total IgE assays, the 3rd WHO International Standard (3rd WHO IRR) for serum IgE (11/234).
No change of Intended Use/Indications for Use or fundamental scientific technology of the assay system has been made. No change of specifications or manufacturing methods for any assay reagents has been made.

Directions for Use for ImmunoCAP Specific and ImmunoCAP Total IgE will be updated to reflect the change. The update will be phased in over time. During a transition period Phadia intends to supply an intermediate version of labelling containing traceability information to either the old and new reference material.

Performance characteristics
The New Device, IgE calibrators traceable to 3rd WHO IRR was compared with the Predicate Device, IgE calibrators traceable to 2nd WHO IRR, in two separate studies:

- Concentration determination of two stock solutions used for production of ImmunoCAP Specific IgE Calibrators
- Evaluation of clinical negative and positive patient samples in ImmunoCAP Specific IgE

Conclusion
The safety and effectiveness of the cleared ImmunoCAP Specific and Total IgE systems, intended for the determination of specific and total IgE antibodies, have been established in previous 510(k) submissions. The Reference Material change does not affect the Intended Use or the Indications for Use statements, the fundamental scientific technology, specifications or manufacturing methods of the assays. The verification studies performed demonstrate that the updated ImmunoCAP Specific and Total IgE assays are substantially equivalent to the currently cleared products.