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

January 15, 2016

Phadia AB
Mr. Martin Mann
Sr. Regulatory Affairs Manager
4169 Commercial Avenue
Portage, MI 49002

Re: K151029
Trade/Device Name: ImmunoCAP Specific IgE
Regulation Number: 21 CFR 866.5750
Regulation Name: Radioallergosorbent (RAST) immunological test system
Regulatory Class: Class II
Product Code: DHB
Dated: December 21, 2015
Received: December 22, 2015

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 yours,

Leonthena R. Carrington -S

Leonthena R. Carrington, MS, MBA, MT(ASCP)
Director
Division of Immunology and Hematology Devices
Office of In Vitro Diagnostics and Radiological Health
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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)*
K151029

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 the instrument 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:	**K151029**
Date of Summary Preparation:	October 29, 2015
Submitter:	Phadia AB
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US Distributor:	Phadia US Inc.
	4169 Commercial Avenue
	Portage, MI 49002
Device Name:	ImmunoCAP Specific IgE
Common Name:	Automated in vitro quantitative assay for the measurement of allergen specific IgE antibodies
Classification:	Class II
Product Code:	(82) DHB
Regulation:	21 CFR 866.5750
Predicate Device:	ImmunoCAP Specific IgE, K113841

Device Description
Description of ImmunoCAP Specific IgE Assay
ImmunoCAP Specific IgE assay measures IgE antibodies to specific allergens in human serum or plasma. Presence of specific IgE antibodies is a prerequisite for an IgE-mediated allergic reaction to occur. The assay allows quantitative measurements of IgE antibodies specific to a wide range of individual allergens and allergen components.
Today, 367 different ImmunoCAP Allergens are cleared in the US for determinations of specific IgE antibodies.

ImmunoCAP Specific IgE is to be used with the 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.

Description of Instruments and software
ImmunoCAP Specific IgE assay is designed to be performed on the Phadia instruments, Phadia 100 and Phadia 250 and on the higher throughput/capacity instruments Phadia 1000, Phadia 2500 and Phadia 5000, along with the general, test and method specific reagents as well as instrument software (ISW) and data management software, Phadia Information Data Management (IDM) or Phadia Prime.

The current version of the new software, Phadia Prime 1.3, is compatible with Phadia 250 and Phadia 1000.

Phadia Prime is PC software running on the Microsoft Windows operating system. It handles requests, results, calculations, and statistics for Phadia Laboratory Systems (Phadia 250 and Phadia 1000) and all currently cleared ImmunoCAP and EliA assays, and is necessary for operation. Several Phadia instruments, same or of different type, can be connected to one PC running Phadia Prime.

Phadia Prime also handles communication with Laboratory Information Systems (LIS). Phadia Prime can be connected to Phadia LabCommunity software for remote control, troubleshooting and support of Phadia Prime and connected Phadia instruments.

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 the instrument 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.

Predicate Device Comparison
No changes have been made to the ImmunoCAP Specific IgE assay, as described in K113841 (and previously cleared under K051218) or its intended use. The list of reagents used in the assay presented in the DfU is unchanged.

Phadia Prime serves the same purpose for Phadia instruments as IDM. They are intended to be used together with Phadia Laboratory Systems in clinical laboratories. The software handles test requests, results, calculations, and statistics for dedicated in vitro diagnostic tests. The software may also be used for communication with other dedicated systems in clinical laboratories, such as Laboratory Information Systems.

Phadia Prime and IDM handle communication with various Laboratory Information Systems (LIS). They can also be connected to Phadia LabCommunity software for remote control, troubleshooting and support of software and connected Phadia instruments.

The reason for the software modification is that the development tools used for the current IDM are no longer supported and therefore the software is being moved into a more efficient development environment.

The main differences between the respective software Phadia Prime and IDM are; IDM is mainly intended to be used with Windows versions up to Windows XP, whereas Phadia Prime runs on Windows versions starting from Windows 7 (SP1); The user interface is slightly updated for Phadia Prime (e.g. support for large screens and a search function included in the Reference Guide); Phadia Prime does not manage all of the LIS formats that IDM manages; Phadia Prime supports Phadia 250 and Phadia 1000, whereas IDM supports also Phadia 100, Phadia 2500, and Phadia 5000; Phadia Prime does not yet support Laboratory Automation System mode.

The main functionalities of the respective software are the same and the same algorithms are used in Phadia Prime for the handling of requests, results, calculations and statistics for the dedicated in vitro diagnostic tests, as in IDM.

The implementation of the software has been fully verified and found acceptable. A comparative test has been performed for Phadia Prime and IDM using a predetermined set of data with instrument raw values and different method settings (assays). The results show that Phadia Prime produces the same output as IDM irrespective of assay chosen.

Conclusion

Based on the information provided above, Phadia believes that the candidate device ImmunoCAP Specific IgE Assay, used with Phadia Prime, is substantially equivalent to Phadia's ImmunoCAP Specific IgE Assay predicate device, used with IDM, cleared under K113841.

The differences between Phadia Prime and IDM are considered minor (some features available in IDM are currently not yet implemented in Phadia Prime) and do not raise different questions of safety and effectiveness. The candidate device is as safe and effective as the predicate device.

The substantial equivalence of the candidate device is based on the similarities in intended use, operational characteristic and the same fundamental design and technology as compared to Phadia's ImmunoCAP Specific IgE Assay predicate device.

The statement above is applicable for all the currently cleared ImmunoCAP and EliA assays.