DEC 1 5 2010

## Summary of Safety and Effectiveness

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) Number:** k100999

**Date of Summary Preparation:** March 24, 2010

**Distributor:**
Phadia US Inc.
4169 Commercial Avenue
Portage, MI 49002
269-492-1957

**Manufacturer:**
Phadia AB
Rapsgatan 7P
SE-754 50 Uppsala, Sweden

**Company Contact Person:**
Martin Mann
Regulatory Affairs Manager
Phadia US Inc.
4165 Commercial Avenue
Portage, MI 49002
269-492-1957

**Device Name:** ImmunoCAP Allergen f20, Almond

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

**Classification:**

| Product Name | Product Code | Class | CFR |
|---|---|---|---|
| ImmunoCAP Allergen f20, Almond | DHB | II | 866.5750 |

| Substantial Equivalence to: | | |
|---|---|---|
| | UniCAP 100 | (k962274) |
| | ImmunoCAP Specific IgE | (k051218) |

**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. 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, as well as physician office laboratories.

## General 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

ImmunoCAP 100$^{e}$, ImmunoCAP 250 and ImmunoCAP 1000 instruments with built-in software process all steps of the assay and print 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.

### Device Description:

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 update of ImmunoCAP Allergen f20, Almond. No changes are made to the Intended Use or in the Indications for Use statements.

The updated version of ImmunoCAP Allergen f20, Almond was verified in a comparison study between the currently cleared and the updated ImmunoCAP Allergen f20, Almond. In the comparison study clinical and positive samples, as well as samples from healthy, non-atopic donors were used. Inhibition studies verified the immunological specificity of almond specific IgE antibody binding.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
10903 New Hampshire Avenue
Document Mail Center – WO66-0609
Silver Spring, MD 20993-0002

Phadia AB
c/o Mr. Martin Mann
Regulatory Affairs Manager
Phadia US, Inc.
4169 Commercial Ave.
Portage, MI 49002

DEC 15 2010

Re: k100999
Trade/Device Name: ImmunoCAP Allergen f20, Almond
Regulation Number: 21 CFR §866.5750
Regulation Name: Radioallergosorbent (RAST) Immunological Test System
Regulatory Class: Class II
Product Codes: DHB
Dated: December 09, 2010
Received: December 13, 2010

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.

If your device is classified (see above) into class II (Special Controls), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. 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); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820). This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Parts 801 and 809), please contact the Office of *In Vitro* Diagnostic Device Evaluation and Safety at (301) 796-5450. 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 Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Maria M. Chan, Ph.D.
Director
Division of Immunology and Hematology Devices
Office of *In Vitro* Diagnostic Device Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

# Indication for Use

DEC 15 2010

510(k) Number (if known): **k100999**

Device Name: **ImmunoCAP Allergen f20, Almond**

Indication for Use:

ImmunoCAP Specific IgE is an in vitro quantitative assay for the measurement of allergen specific IgE in human serum or plasma. ImmunoCAP Specific IgE is to be used with the instruments ImmunoCAP 100, ImmunoCAP 250 and ImmunoCAP 1000. 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, as well as physician office laboratories.

Prescription Use __√___ (21 CFR Part 801 Subpart D) And/Or Over the Counter Use ____. (21 CFR Part 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE; CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Device Evaluation and Safety (OIVD)

Division Sign-Off
Office of In Vitro Diagnostic Device
Evaluation and Safety

510(k) k100999