MAR 1 3 2009

Phadia

510(k) Summary

510(k) Number: k081830

Date of Summary preparation: March 9, 2009

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

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

Company contact person:
Martin Mann
Regulatory Affairs Manager
Phadia US Inc
4169 Commercial Avenue
Portage, MI 49002
Telephone 269-492-1957

Device Name:
ImmunoCAP® Rapid System:
- ImmunoCAP® Rapid Inhalant Profile 1
- ImmunoCAP® Rapid Reader
- ImmunoCAP® Rapid Reader Check Device
- ImmunoCAP® Rapid QC 1

Common name:
In vitro diagnostic system for the determination of allergen specific IgE antibodies

Classification:
Regulation Number: 21 CFR 866.5750
Product Class: Class II
Product Code: DHB

Substantial Equivalence to:
ImmunoCAP® Specific IgE (K962274)

Intended Use

ImmunoCAP Rapid Inhalant Profile 1, part of the ImmunoCAP Rapid System, is an in vitro semi-quantitative assay for measurement of allergen specific IgE to ten inhalant allergens (house dust mite, cat, dog, mold, and pollen from common ragweed, Bermuda grass, timothy grass, oak, and elm) in heparinized human capillary whole blood, heparinized venous whole blood, or heparinized 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, licensed under CLIA to perform nonwaived assays.

General Description

ImmunoCAP Rapid System is a combination of lateral flow immunoassay reagents and instrument/software for semi-quantitative determination of antibodies or antigens in human capillary whole blood, heparinized venous whole blood or heparinized plasma.

ImmunoCAP Rapid System currently consists of the following:

- ImmunoCAP Rapid Inhalant Profile 1 - a kit for measuring specific IgE antibody levels to 10 inhalant allergens (house dust mite, cat epithelium and dander, dog dander, mold, and pollen from common ragweed, Bermuda grass, timothy grass, oak, and elm).
- ImmunoCAP Rapid Reader - an instrument for reading and scoring the test results.
- ImmunoCAP Rapid Reader Check Device - an external positive and negative Reader control for regular checks of instrument performance.
- ImmunoCAP Rapid QC 1 - a kit containing external positive and negative specific IgE system controls to be performed with recommended frequency.

Principle of the test

ImmunoCAP Rapid Inhalant Profile 1 is a lateral flow immunoassay for the semi-quantitative measurement of allergen specific IgE antibodies in human whole blood or plasma. Ten different allergens are bound to the strips in the Test Windows in separate lines. IgE antibodies present in the patient sample, specific to any of the allergens in the test, bind to the relevant allergen lines on the strips. In a single step, a gold labeled anti-IgE conjugate is solubilized, migrates up the strips and forms a visible red complex with bound IgE antibodies while unbound IgE is washed away. The conjugate continues to migrate, forming visible red lines in the Control Windows. The Reader measures the color saturation of the red lines and scores them as Class 1, 2 or 3. The higher the concentrations of specific IgE antibodies present in the patient sample the higher the obtained Class value.

Summary of performance testing

Comparison studies, including in total 245 donors, were performed to demonstrate that results obtained from ImmunoCAP Rapid Inhalant Profile 1 (New Device) are substantially equivalent to ImmunoCAP Specific IgE results (Predicate Device). In addition, the studies were designed to demonstrate that capillary and venous whole blood and plasma are interchangeable samples in the New Device.
Heparinized capillary and venous whole blood were collected from all donors. Plasma was processed from the venous whole blood. All three sample types were used in the New Device and plasma only was used in the Predicate Device, based on the Directions for Use.
For all matrices used in the New Device, when compared to the Predicate Device, the obtained the overall agreement within Classes was $\geq 91\%$.
The studies also demonstrated that capillary and venous whole blood and plasma are interchangeable samples in the New Device.

Variation between Assay Devices, occasions, lots, sites and operators was studied.
The total variation of ImmunoCAP Inhalant Profile 1 including Assay Device, occasion, lot-lot and sites is below 20% CV.

The Limit of Detection for each of the ten allergens in ImmunoCAP Rapid Inhalant Profile 1 was found to be within Class 1, thus below 1 kU_A/L.

The conjugate anti-IgE-antibody did not cross react with other human immunoglobulin IgG1, IgG2, IgG3, IgG4, IgA, IgM and IgD.

Studies of potentially interfering substances showed no influence of total IgE, hemoglobin, heparin, bilirubin, and Chyle, on ImmunoCAP Rapid Inhalant Profile 1 results.

Conclusion

The performed studies demonstrate that the New Device, ImmunoCAP Inhalant Profile 1, part of the ImmunoCAP Rapid System, is substantially equivalent to the Predicate Device, ImmunoCAP Specific IgE laboratory test.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

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

MAR 13 2009

Re: k081830
Trade/Device Name: ImmunoCAP® Rapid System
ImmunoCAP® Rapid Inhalant Profile 1
ImmunoCAP® Rapid Reader
ImmunoCAP® Rapid Reader Check Device
ImmunoCAP® Rapid QC 1
Regulation Number: 21 CFR 866.5750
Regulation Name: Radioallergosorbent (RAST) Immunological Test system
Regulatory Class: Class II
Product Code: DHB
Dated: February 20, 2009
Received: February 23, 2009

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 either class II (Special Controls) or class III (PMA), 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); 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 Part 801), please contact the Office of In Vitro Diagnostic Device Evaluation and Safety at (240) 276-0450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (240) 276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at (240) 276-3464. 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 (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Maria M Chan

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

Indications for Use

510(k) Number (if known): k081830

Device Name: ImmunoCAP® Rapid Inhalant Profile 1

Indications For Use:

ImmunoCAP Rapid Inhalant Profile 1, part of the ImmunoCAP Rapid System, is an in vitro semiquantitative assay for measurement of allergen specific IgE to ten inhalant allergens (house dust mite, cat, dog, mold, and pollen from common ragweed, Bermuda grass, timothy grass, oak, and elm) in heparinized human capillary whole blood, heparinized venous whole blood, or heparinized 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, licensed under CLIA to perform nonwaived assays.

Prescription Use X AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

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

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

Division Sign-Off

Office of In Vitro Diagnostic
Device Evaluation and Safety

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