510(k) SUBSTANTIAL EQUIVALENCE DETERMINATION
DECISION SUMMARY

A. 510(k) Number:
k092978

B. Purpose for Submission:
Device modification to k081830. New imaging aid to the existing device.

C. Manufacturer and Instrument Name:
Phadia AB, ImmunoCAP® Rapid Reader

D. Type of Test or Tests Performed:
Semi-quantitative, lateral flow immunoassay

E. System Descriptions:

1. Device Description:

The ImmunoCAP® Rapid Reader is part of ImmunoCAP® Rapid System, which is a combination of lateral flow immunoassay reagents and instrument/software for semi-quantitative determination of IgE antibodies in human capillary whole blood, heparinized venous whole blood or heparinized plasma.
The Rapid Reader is a stand alone instrument to be used with ImmunoCAP Rapid Assay Device. It consists of the Rapid Reader instrument and associated software. The user interface consists of a LCD display with a touch screen and a slot for insertion of the ImmunoCAP Rapid Assay Device. The Reader includes functions for photometric reading and scoring of the test results. The Assay Device is illuminated with white color spectrum LED's. A sensor records an image of the Assay Device including Test and Control Windows, and reads the color saturation (Color Units).

Software: The built in software performs the control checks and the necessary calculations to convert Color Units to Class scores. Patient or external control results are displayed and printed only if internal Reader controls and Assay Device controls are valid.

Assay Device docking system: The slot for the ImmunoCAP Rapid Assay Device has one optical switch for interaction with the Assay Device to initiate reading and system checks.

Camera, optics, and light source: The camera is a CMOS camera with a pixel resolution of 2048 x 1536. The light source consists of four, white color spectrum LEDs placed behind four diffusers, to ensure even illumination of the reading area on the Assay Device.

Computer system and power supply: Integrated microprocessor with a 45W input 100-240V ~ 1.2A 50-60 Hz power supply.

Display and touch screen: The user interface consists of a LCD panel with 480 x 272 pixel resolution, with included touch interface functionality.

Printer: Built in thermal printer for automatic printing of assay results.

2. Principles of Operation:
   The Reader includes functions for photometric reading and scoring of the test results. The Assay Device is illuminated with white color spectrum LED's. A sensor records an image of the Assay Device including Test and Control Windows, and reads the color saturation (Color Units). The built in software performs the control checks and the necessary calculations to convert Color Units to Class scores. Patient or external control results will be displayed and printed only if internal Reader controls and Assay Device controls are valid.
   The ImmunoCAP Rapid Reader quantitatively measures the color saturation and converts the signal into Color Units (CU). The higher the concentration of IgE antibodies in the sample the stronger the color of the red lines, i.e. higher CU values. CU values are then categorized semiquantitatively into Class 1, 2 or 3. The user performs the Rapid assay according to the instructions for use and inserts the Assay Device into the Rapid Reader as shown on the screen of the Reader. If the necessary control conditions are met, assay results will be displayed on the screen and automatically printed. If the Reader does not detect the blood sample or the assay control lines are missing, the Rapid Reader will not report or print any results. The Reader displays results as Class 1, 2 or 3 for each allergen.
3. Modes of Operation:
   Semi-automated. No change from the predicate device.
4. Specimen Identification:
   Manual input by user.. No changes from the Predicate Device.
5. Specimen Sampling and Handling:
   Samples should be obtained and handled according to the laboratory's standard operating procedures and following the protocol described in the package insert. No changes from the Predicate Device.
6. Calibration:
   ImmunoCAP Rapid Reader is calibrated at manufacturing and does not require any user calibration. No changes from the Predicate Device.
7. Quality Control:
   The performance of ImmunoCAP Rapid Reader is verified at regular intervals through the use of the Check Device. No changes from the Predicate Device.
8. Software:
   FDA has reviewed applicant's Hazard Analysis and Software Development processes for this line of product types:
   Yes__X___ or No_____

F. Regulatory Information:

1. Regulation section:
   21 CFR § 866.5750, Radioallergosorbent (RAST) immunological test system
2. Classification:
   Class II

3. Product code:
   DHB System, Test, Radioallergosorbent (RAST), Immunological
4. Panel:
   Immunology (82)

G. Intended Use:

1. Indication(s) for Use:
   ImmunoCAP Rapid Reader, part of ImmunoCAP Rapid System, is an instrument including software to be used for reading and scoring ImmunoCAP Rapid assay results. It is intended for in vitro diagnostic use and is to be used in clinical laboratories, licensed under CLIA to perform non-waived assays.
2. Special Conditions for Use Statement(s):
   For prescription only

H. Substantial Equivalence Information:

1. Predicate Device Name(s) and 510(k) numbers:
   ImmunoCAP Rapid Reader, k081830
2. Comparison with Predicate Device:

Similarities		
Item	Device	Predicate
Intended Use	ImmunoCAP Rapid Reader, part of ImmunoCAP Rapid System, is an instrument including software to be used for reading and scoring ImmunoCAP Rapid assay results. It is intended for in vitro diagnostic use and is to be used in clinical laboratories, licensed under CLIA to perform non-waived assays.	same
System Configuration	ImmunoCAP® Rapid System, is an *in vitro* semi-quantitative assay for measurement of allergen specific IgE to inhalant in heparinized human capillary whole blood, heparinized venous whole blood, or heparinized plasma. ImmunoCAP® Rapid System consists of the ImmunoCAP® Rapid	same

Similarities		
Item	Device	Predicate
	Reader, ImmunoCAP® Rapid Reader Check device, ImmunoCAP® Rapid Inhalant Profile 1, and ImmunoCAP® RapidQC 1.	
Reader Functionalities	The Reader is a stand alone instrument to be used with ImmunoCAP Rapid Assay Device. The user interface consists of a LCD display with a touch screen and a slot for insertion of the ImmunoCAP Rapid Assay Device.	same
Analysis of assay results from a whole blood sample	Performed in default mode by measuring color saturation of assay results	Same
Analysis of assay results from a QC/plasma sample	Performed in QC/plasma mode (after pressing the QC/plasma button) by measuring color saturation of assay results	Same
Reader performance check	Mandatory after 7 days and is performed by inserting the Check Device	Same
Setting of date and time	Performed from Settings menu displayed on the touch screen	Same

Differences		
Item	Device	Predicate
Reader hardware components	**Hardware updated Reader**	**Hardware current Reader**
Assay Device docking system	One optical switch	Two mechanical switches
Light source	Four white color spectrum LED's and four diffusers	Four white color spectrum LED's and two optical diffusers
Camera	CMOS camera with	CCD camera with

Differences		
Item	Device	Predicate
	2048x1536 pixel resolution	1024x768 pixel resolution
Computer system, hard disk	Microprocessor	Mini-PC
Power supply	45W input 100-240V ~ 1.2A 50-60 Hz	65W input 100-240V ~ 1.6A 50-60 Hz
Display and Touch screen	LCD panel resolution 480x272	LCD panel resolution 640x480
Printer	Built-in thermo printer	Separate thermo printer
Weight and Footprint (WxDxH in mm)	1.0 kg 237x117x147	5.8 kg 214x178x252
Software Feature	Updated Reader Software	Current Reader Software
Printing of results	Automatic after completion of analysis	User initiated printing
Programming language	C and C++	C and Octave
Setting up/communicating with peripheral components, handle file systems, signals and task scheduling	Linux kernel 2.6.22.6	Linux kernel 2.6.20
Set up RAM, CPU registers and clocks, and start Linux kernel	Redboot	BIOS (Basic input/output system) in PC
Framework for Graphical User Interface.	Qt	GTK+ and Cairo
Library to convert to printer data format	Ghostscript	CUPS

I. Special Control/Guidance Document Referenced (if applicable):

CLSI EP17- Protocols for Determination of Limits of Detection and Limits of Quantitation

Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices - Guidance for Industry and FDA Staff

Radioallergosorbent Test (RAST) Methods for Allergen-Specific Immunoglobulin E (IgE) 510(k)s; Final Guidance for Industry and FDA

J. Performance Characteristics*:*

1. Analytical Performance:

   a. Method Comparison:

   The performance of the Reader in reading the level of IgE antibodies to each of ten allergens (house dust mite, cat, dog, mold, and pollen from common ragweed, Bermuda grass, timothy grass, oak, and elm) was compared to the predicate device and agreement between the two methods was assessed. The comparison

study shows that the new device is in agreement with the predicate device when measuring IgE levels in either whole blood or plasma.

i) Whole Blood Comparison Study: Heparinized capillary whole blood was collected from 134 donors. Each sample was tested with one ImmunoCAP Rapid Inhalant Profile 1 Assay Device according to Directions for Use. After completion of the assay, each Assay Device was read in both the New and the Predicate Device.

New Device compared to Predicate Device using whole blood samples.

Allergen	NPA %	Lower 95% CI %	Upper 95% CI %	PPA %	Lower 95% CI %	Upper 95% CI %	Overall agreement %	Number Of measurements
e1	96	88	99	97	89	100	96	134
d1	96	88	99	98	91	100	97	134
g2	99	93	100	100	94	100	99	134
w1	95	88	99	92	81	98	94	134
t7	99	93	100	95	86	99	97	134
m6	100	96	100	98	87	100	99	134
g6	98	88	100	98	92	100	98	134
t8	93	86	98	100	92	100	96	134
e5	98	92	100	91	78	97	96	134
d2	100	95	100	97	89	100	99	134
All	97	96	98	97	95	98	97	1340

ii. Plasma Comparison Study: In-house plasma samples from 239 sensitized donors with measurable specific IgE levels to one or more of the allergens in ImmunoCAP Rapid Inhalant Profile 1. All samples were run according to ImmunoCAP Rapid Inhalant Profile 1 Directions for Use. After completion of the assay, each Assay Device was read in both the New and the Predicate Device.

New Device compared to Predicate Device using plasma samples.

Allergen	NPA %	Lower 95% CI %	Upper 95% CI %	PPA %	Lower 95% CI %	Upper 95% CI %	Overall agreement %	Number of measurements
e1	100	97	100	97	92	99	99	239
d1	99	96	100	89	80	94	95	239

g2	98	94	100	94	87	98	97	239
w1	98	94	100	99	96	100	99	239
t7	98	94	100	96	90	99	97	239
m6	100	98	100	100	94	100	100	239
g6	97	91	99	99	95	100	98	239
t8	99	97	100	98	91	100	99	239
e5	99	97	100	99	92	100	99	239
d2	100	98	100	98	891	100	99	239
All	99	96	99	97	95	98	98	2390

b. Precision/Reproducibility:
The sponsor performed a precision study using a special pre-prepared Assay Device to estimate the variation within and between Readers. The Assay Device was constructed using the same plastic housing device as in ImmunoCAP Rapid Inhalant Profile 1, but replacing the allergen strips with pre-prepared strips with 5 defined colored areas. The same pre-prepared Assay Device was read by 3 different Readers in 30 replicates. The Color Units (CU) values were recorded for each reading and the variation within and between Readers was estimated using a one-way analysis of variance model and the estimated components expressed as CV%.

Table below show the Coefficients Variance (CV%) for a pre-colored Assay Device read in 3 different Readers in 30 replicates and measured as Color Units (CU). As shown in the table below, % CV between readers varied from 0.46 to 2.69 and within readers varied from 0.3 to 2.43. The total CV% varied from 0.59 to 3.63.

Line	Corresponding allergen position	Number of Readings	CU Mean	CV% Between Readers	CV% Within Readers	CV% Total	CV% Total
Left 1	e1	90	24.02	1.09	0.41	1.06	1.06
Left 2	d1	90	11.92	0.81	0.42	0.59	0.59
Left 3	g2	90	7.64	0.75	0.40	0.91	0.91
Left 4	w1	90	2.74	0.97	0.78	1.14	1.14
Left 5	t7	90	0.57	0.74	2.29	3.63	3.63
Right 1	m6	90	23.27	1.01	0.30	1.16	1.16
Right 2	g6	90	11.89	0.46	0.37	0.91	0.91

Right 3	t8	90	7.42	0.81	0.42	0.85	0.85
Right 4	e5	90	2.72	0.92	0.68	1.25	1.25
Right 5	d2	90	0.58	2.69	2.43	2.41	2.41
Total		900		1.18	1.15	1.64	1.64

c. Linearity: Not applicable.

d. Carryover: Not applicable (This device does not come into contact with analytical samples.)

e. Interfering Substances: Not applicable (Interfering substances are a property of the Assay Device and not the Reader.)

2. Other Supportive Instrument Performance Data Not Covered Above:

Limit of Blank/Limit of Detection (LoD and LoB for each allergen and total)

Allergen	LoB (Mean CU)	LoD (Mean CU)
e1	0.056	0.073
d1	0.192	0.256
g2	0.086	0.123
w1	0.112	0.159
t7	0.106	0.146
m6	0.129	0.181
g6	0.085	0.123
t8	0.092	0.129
e5	0.077	0.107
d2	0.118	0.157
Total	**0.131**	**0.183**

Comparison of total LoB and total LoD as measured by New and Predicate Device

Reader	LoB (CU) Mean	LoB (CU) 95th Percentile	LoD (CU) Mean	LoD (CU) 95th Percentile
New device	0.13	0.15	0.18	0.20
Predicate device	0.16*	0.16*	0.22*	0.22*

*Values from K081830

K. Proposed Labeling:

The labeling is sufficient and it satisfies the requirements of 21 CFR Part 809.10.

L. Conclusion:

The submitted information in this premarket notification is complete and supports a substantial equivalence decision.