MAR 1 1 2009

SUMMARY OF SAFETY AND EFFECTIVENESS

Assigned 510(k) Number

The assigned 510(k) number is K083314.

Sponsor Name and Address

Siemens Healthcare Diagnostics Inc.
5210 Pacific Concourse Drive
Los Angeles, CA
90045-6900
(310) 645-8200

Contact

Clare Santulli
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Device Name

Trade name:	IMMULITE® 2000 3gAllergy™ Specific IgE Assay
Classification:	Class II
Classification Names:	Radioallergosorbent (RAST) Immunological Test System
Regulation Number:	866.5750
Product Code:	DHB
Catalog Numbers:	L2KUN6 (600 tests)

Description of Device

IMMULITE® 2000 3gAllergy™ Specific IgE is a solid-phase, two-step, chemiluminescent immunoassay that exploits liquid phase kinetics in a bead format.[1,2] (U.S. Patent No. 4,778,751) It represents a significant advance over conventional methods relying on allergens attached to a solid-phase support, such as a paper disk.

The allergens are covalently bound to a soluble polymer/co-polymer matrix, which in turn is labeled with a ligand. The use of an amino acid co-polymer amplifies the amount of allergen that the matrix can support.

Incubation Cycles: 2 × 30 minutes.

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[1] El Shami AS, Alaba O. Liquid-phase *in vitro* allergen-specific IgE assay with *in situ* immobilization. Adv Biosci 1989;74:191–201.

[2] Alaba O, El Shami AS. Evaluation of non-specific IgE binding: comparison of two *in vitro* allergen assays. Adv Biosci 1989;74:203–14.

Indications for Use

For *in vitro* diagnostic use with the IMMULITE® 2000 Analyzer — for the quantitative measurement of allergen-specific IgE in human serum, as an aid in the clinical diagnosis of IgE-mediated allergic disorders.

Establishment Information

IMMULITE® 2000 3gAllergy Specific IgE assay is manufactured by Siemens Healthcare Diagnostics Inc. at the following locations:

Siemens Healthcare Diagnostics Inc.
5210 Pacific Concourse Drive
Los Angeles, CA 90045-6900
FDA Establishment #: 3005250747

Predicate

The purpose of this 510(k) submission is for clearance of 6 additional specific allergens, named in the table below, to be used with the IMMULITE® 2000 3gAllergy™ Specific IgE on the IMMULITE® 2000 analyzer.

1	RED MAPLE
2	WHITE HICKORY
3	RED CEDAR
4	SWEET GUM
5	COMMON SAGEBRUSH
6	WING SCALE

FDA clearance was previously obtained for the assay kit and 196 specific allergens and allergen panels (K013134, K021206, K013135 and K021208).

Please note that the FDA clearances indicated above were in the name of Diagnostic Products Corporation which was acquired by Siemens Medical Solutions Diagnostics in July 2006. Siemens Medical Solutions Diagnostics was renamed Siemens Healthcare Diagnostics Inc. on January 1, 2008.

Precision

Precision studies were performed in accordance with Clinical Laboratory Standard Institute (CLSI) guidance: *Evaluation of Precision Performance of Quantitative Methods; Approved Guideline-Second Edition.* CLSI document EP5-A2 (ISBN 1-56238-542-9). CLSI, 940 West Valley Road, Suite 1400, Wayne, Pennsylvania 19087-1898 USA, 2004 assaying two aliquots of each test sample in two runs per day on 20 different days. Analysis of variance was used to estimate the within-run and total precision.

Three allergen lots were tested using three positive samples and one negative sample. Intra-assay and inter-assay precision for the positive samples were evaluated by calculating the kU/L dose percent coefficients of variation (%CV) for each positive sample. Non-specific binding (NSB) was monitored by testing the negative control sample.

Representative precision claims for each allergen tested are presented below:

Allergen Precision Claims*

Sample	Mean	Within-Run SD	Within-Run CV	Total SD	Total CV
	kU/L	kU/L	%	kU/L	%
Allergen = Red Maple, Lot 110					
Positive #1	2.17	0.073	3.36	0.117	5.39
Positive #2	3.19	0.096	3.01	0.162	5.08
Positive #3	12.06	0.452	3.75	0.634	5.26
Allergen = White Hickory, Lot 111					
Positive #1	1.12	0.038	3.39	0.053	4.73
Positive #2	4.54	0.238	5.24	0.312	6.87
Positive #3	6.25	0.214	3.42	0.267	4.27
Allergen = Red Cedar, Lot 110					
Positive #1	1.34	0.056	4.18	0.071	5.30
Positive #2	7.63	0.393	5.15	0.421	5.52
Positive #3	10.09	0.521	5.16	0.560	5.55
Allergen = Sweet Gum, Lot 110					
Positive #1	2.70	0.082	3.04	0.139	5.15
Positive #2	3.00	0.115	3.83	0.154	5.13
Positive #3	7.97	0.332	4.17	0.502	6.30
Allergen = Common Sagebrush, Lot 111					
Positive #1	1.42	0.049	3.45	0.069	4.86
Positive #2	4.14	0.191	4.61	0.291	7.03
Positive #3	10.47	0.425	4.06	0.558	5.33
Allergen = Wingscale, Lot 113					
Positive #1	1.56	0.056	3.59	0.072	4.62
Positive #2	5.20	0.246	4.73	0.267	5.13
Positive #3	9.81	0.324	3.30	0.424	4.32

* data are representative of one lot on one instrument

Linearity

For each allergen, two samples were diluted in 2-fold serial dilutions to 5 levels. The undiluted (neat) and diluted samples were tested with the specific allergen to demonstrate linearity at concentrations within the assay limits. Regression statistics for each allergen comparing observed to expected data are presented below.

Linearity

Allergen	Regresion Equation	N	Slope	95% CI	Intercept	95% CI
Red Maple	Y= 1.00X + 0.06	12	0.999	0.961–1.037	0.059	–0.124-0.242
White Hickory	Y= 1.00X + 0.06	12	1.004	0.981–1.028	0.062	–0.122-0.246
Red Cedar	Y= 1.00X – 0.01	12	1.003	0.987–1.019	–0.007	–0.081-0.067
Sweet Gum	Y= 1.00X + 0.31	12	0.997	0.965–1.029	0.306	0.051-0.561
Common Sagebrush	Y= 1.00X + 0.62	12	0.999	0.970–1.028	0.615	–0.400-1.270
Wingscale	Y= 1.00X – 0.10	12	0.998	0.981–1.015	–0.098	–0.252-0.056

Specificity (Inhibition) Studies

Specificity of each allergen was verified through competitive inhibition testing using a single serum sample or pool of sera. A negative sample was used to measure the background response.

To initiate the inhibition experiment, 70µL of undiluted and 4 levels of 5-fold serially diluted inhibitor extract were mixed with 250µL of sample or pool. This mixture was incubated at room temperature (15-28 °C) for 1 hour allowing the immunological reaction to occur. Each sample mixture containing the inhibitor extract and the appropriate controls was assayed with 1 lot of each allergen. The percent (%) inhibition was calculated according to the following formula:

$$\frac{(\text{Response of pos. control}_{(\text{pos. sample} - \text{neg. sample})} - \text{sample response with inhibitor extract})}{(\text{Response of pos. control}_{(\text{pos. sample} - \text{neg. sample})})} \times 100$$

The inhibition study demonstrated that the allergens tested are inhibited by the relevant inhibitor extract in a concentration dependent fashion. Also, the target % inhibition of 50% was met. These results indicate specificity of the red maple, white hickory, red cedar, sweet gum, common sagebush and wingscale specific allergens. Summary inhibition table is presented below.

Red Maple		White Hickory		Red Cedar	
Inhibitor Concentration (mg/mL)	% Inhibition	Inhibitor Concentration (mg/mL)	% Inhibition	Inhibitor Concentration (mg/mL)	% Inhibition
5	100.00	5	100.00	5	97.59
1	99.04	1	100.00	1	93.78
0.2	96.83	0.2	97.87	0.2	83.63
0.04	79.15	0.04	89.03	0.04	70.98
0.008	0.00	0.008	27.33	0.008	69.28

Sweet Gum		Common Sagebush		Wingscale	
Inhibitor Concentration (mg/mL)	% Inhibition	Inhibitor Concentration (mg/mL)	% Inhibition	Inhibitor Concentration (mg/mL)	% Inhibition
5	98.53	5	100.00	5	87.49
1	96.07	1	100.00	1	72.05
0.2	92.61	0.2	100.00	0.2	38.26
0.04	68.03	0.04	89.71	0.04	20.46
0.008	10.15	0.008	69.61	0.008	5.30

Clinical Studies

Clinical performance of the allergens was demonstated by testing samples from non-atopic individuals and samples from atopic patients with case histories of suspected clinical reactions to the specific allergen or allergy group in the IMMULITE® 2000 3gAllergy Specific IgE assay and comparing results to accompanying clinical information.

Data summary agreement of the IMMULITE® 2000 3gAllergy results to clinical data is presented in the table below.

IMMULITE® 2000	Clinical Data				
	Clinical	Normal	Total		
Positive	196	37	233		
Negative	92	775	867		
Total	288	812	1,100		
		95.4%	88.3%		
		Specificity	Agreement		
Allergens included: Common Sagebrush, Wingscale, Red Maple, White Hickory, Sweet Gum, Red Cedar					

IMMULITE® 2000 3gAllergy assay results for all allergens compare well with clinical documentation of presence or absence of signs, symptoms and other diagnostic evidence of allergen sensitivity.

Conclusions for all Studies

Allergens including red maple, white hickory, red cedar, sweet gum, common sagebrush, and wingscale for use with the IMMULITE® 2000 3gAllergy Specific IgE assay demonstrate acceptable analytical performance including precision, linearity and specificity. IMMULITE® 2000 assay results compare well with clinical documentation of presence or absence of signs, symptoms and other diagnostic evidence of allergen sensitivity. Substantial equivalence was demonstrated to clinical data, supporting the following intended use of the IMMULITE® 2000 3gAllergys Specific IgE assay and the 6 previously listed allergens:

> For *in vitro* diagnostic use with the IMMULITE® 2000 Analyzer — for the quantitative measurement of allergen-specific IgE in human serum, as an aid in the clinical diagnosis of IgE-mediated allergic disorders.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

MAR 1 1 2009

Siemens Healthcare Diagnostics Inc.
c/o Ms. Claire Santulli
Senior Regulatory Affairs Specialist
511 Benedict Avenue
Tarrytown, New York 10591

Re: k083314
Trade/Device Name: IMMULITE® 2000 3gAllergy ™ Specific IgE Assay
Regulation Number: 21 CFR 866.5750
Regulation Name: Radioallergosorbent (RAST) Immunological Test System
Regulatory Class: II
Product Code: DHB
Dated: February 12, 2009
Received: February 13, 2009

Dear Ms. Santulli:

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 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). You may, therefore, market the device, subject to the general controls provisions of the Act. However, you are responsible to determine that the medical devices you use as components in the [kit/tray] have either been determined as substantially equivalent under the premarket notification process (Section 510(k) of the act), or were legally on the market prior to May 28, 1976, the enactment date of the Medical Device Amendments. Please note: If you purchase your device components in bulk (i.e., unfinished) and further process (e.g., sterilize) you must submit a new 510(k) before including these components in your kit/tray. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, and 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 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 Part 801); 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.

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 the labeling regulation, 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" (21 CFR Part 807.97). For question 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 many obtain other general information on your responsibilities under the Act from the Division of Small Manufactuers, 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

Indication for Use

510(k) Number (if known): K083314

Device Name: IMMULITE 3gAllergy™ Specific IgE Assay

Indication For Use:

For *in vitro* diagnostic use with the IMMULITE 2000 Analyzer — for the quantitative measurement of allergen-specific IgE in human serum, as an aid in the clinical diagnosis of IgE-mediated allergic disorders.

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) 083314