K983954

DEC 17 1998

510 (k) Summary
Safety and Effectiveness

This summary of safety and effectiveness information has been prepared in accordance with the requirements of SMDA 1990 and 21 CFR Part 807.92.

Name: **Address:**	Diagnostic Products Corporation 5700 West 96th Street Los Angeles, California 90045-5597
Telephone Number: **Facsimile Number:**	(310) 645-8200 (310) 645-9999
Contact Person:	Edward M. Levine, Ph.D. Director of Clinical Affairs
Date of Preparation:	November 4, 1998
Device Name: Trade:	AlaSTAT Microplate Mixed Allergen Panels: AlaSTAT Microplate Food Panel 5 AlaSTAT Microplate Food Panel 6 AlaSTAT Microplate Food Panel 7 AlaSTAT Microplate Dust Panel 1 AlaSTAT Microplate Grass Panel 2 AlaSTAT Microplate Grass Panel 3
Catalog Number:	FP5M, FP6M, FP7M, HP1M, GP2M and GP3M
CFR:	A radioallergosorbent test system is a device system that consists of the reagents used to measure by immunochemical techniques the allergen antibodies (antibodies which cause an allergic reaction specific for a given allergen. Measurement of specific allergen antibodies may aid the diagnosis of asthma, allergies and other pulmonary disorders.
Common:	Allergen Panels for the detection of Allergen-Specific IgE in the AlaSTAT Microplate Allergen-Specific IgE System.
Classification:	Class II device, 82-DHB (CFR 866.5750)
CLIA Complexity Category:	High, based on previous classification of analogous tests.

Manufacturer:

Diagnostic Products Corporation
5700 West 96th Street
Los Angeles, California 90045-5597

Establishment Registration Number:

DPC's Registration Number is 2017183

Substantially Equivalent Predicate Devices:

AlaSTAT Microplate Allergen-Specific IgE

Description of Devices:

The AlaSTAT Microplate Mixed Allergen Panels are clinical devices used for detection of IgE antibodies to specific allergens in serum.

Intended Use of the Devices:

AlaSTAT Microplate Allergen-Specific IgE is a kinetic enzyme immunometric assay system designed for the measurement of allergen-specific IgE in serum. It is intended strictly for *in vitro* diagnostic use as an aid in the clinical diagnosis of IgE-mediated allergic disorders.

Summary and Explanation of the test:

Many allergies are mediated by immunoglobulins of the IgE class. In sensitized individuals suffering from this immediate (atopic or anaphylactic) type of allergy, IgE molecules act as points of contact between the allergen and specialized cells that release histamine and other agents upon exposure to the allergen; this initiates the events which we recognize as allergic reactions. When evaluated in the light of other clinical and laboratory findings, *in vitro* allergen-specific IgE tests can help the physician identify the allergen (or allergens) to which an individual is sensitive.

Performance Equivalence- Technology Comparison:

The AlaSTAT Microplate Mixed Allergen Panels use exactly the same technology used in the AlaSTAT Microplate Allergen-Specific IgE assays.

The AlaSTAT Microplate Allergen-Specific IgE (and therefore the Mixed Allergen Panels) is a liquid-phase immuno-enzymometric assay in a microplate format for the detection of circulating allergen-specific IgE antibodies. The specific allergens are covalently attached to a soluble polymer/copolymer matrix, thus permitting optimum presentation of the determinants to circulating IgE antibodies. Both the Specific Allergen Modules (predicate device) and the Mixed Allergen Panels (510k device submitted) for AlaSTAT Microplate Allergen-Specific IgE allergy tests are performed in the same manner as all other AlaSTAT Microplate Allergen-Specific IgE tests. Test results are given in both kilo-Units per liter (kU/L) and as a Class number.

Use of the AlaSTAT Microplate Allergen-Specific IgE System offers benefits to both the patient and the laboratory. The liquid phase kinetics allows for a more rapid assay and decreases the

Performance Equivalence- Technology Comparison (continued):

probability that steric hindrance will interfere with proper allergen-IgE binding. In addition, the liquid feature of the AlaSTAT Microplate Allergen-Specific IgE System enables exact titering unlike allergens bound to solid surfaces, for which incremental adjustments are not possible. This allows for improved inter-lot precision. The liquid feature also eliminates variability introduced by the solid support itself.

The AlaSTAT Microplate Allergen-Specific IgE System offers patient benefits due to an additional technological difference from allergosorbent type assays. The chemistry of coupling of allergens to the ImmunoCAP necessitates the presence of an amino functional group (NH2) in the chemical structure of the allergen. Coupling to the ImmunoCAP is always through the amino group which is not present in certain allergens. Proteins also contain other functional groups such as hydroxyl groups (OH), thiol groups (SH), and carboxyl groups (COOH). These functional groups are not directly available for coupling in the allergosorbent type of assay, but are available for coupling in the AlaSTAT Microplate Allergen-Specific IgE System. These facts have important implications for the performance of the assay.

First, coupling of the allergen to the support in the allergosorbent type assay necessitates either direct bonding of the amino group to the solid surface or a modification of the allergen so that it may be bound to the solid surface. Either possibility may result in interference in the recognition of the allergen by the allergen-specific antibody. In addition, allergens are often carbohydrates which do not contain amino groups. Carbohydrate allergens can only be directly coupled to paper disc surfaces if the carbohydrate is bound to protein. This, in effect, restricts the ability to detect carbohydrate allergens in the allergosorbent type assay. In the AlaSTAT Microplate Allergen-Specific IgE System, carbohydrates may be coupled via their hydroxyl groups so that allergens may be available for recognition which are not available in any allergosorbent type assay. By coupling allergens through a combination of functional groups in the AlaSTAT Microplate Allergen-Specific IgE System, the user can be assured that all antigens in an allergen extract are presented to the antibody in multiple conformations, increasing the likelihood that proper recognition and binding will take place. Thus, a false positive result (when compared with an allergosorbent type assay) may actually represent the detection of true allergen-specific IgE not detectable by allergosorbent type assays. This represents a benefit to the patient not afforded by other existing technologies.

Finally, the AlaSTAT Microplate Allergen-Specific IgE System increases the potential number of immunocomplexes that can be immobilized on a solid support since only a few ligands need to be attached to the ligand matrix in order to affect complete immobilization of the entire immunocomplex. This results in a greater possible signal generated per binding site on the plate. In addition, many sterically unrestricted allergen molecules are available for binding by specific IgE in close physical proximity to one another, thus making the allergen-IgE binding a more efficient process. Together these and other factors result in the requirement for less allergen per assay than a disc-based assay (provided equipotent allergen extracts are available). Thus, the quantity of allergen present in each assay is not comparable to the amount of allergen present on atypical allergosorbent disc or other solid phase support.

Performance Equivalence-Method Comparison:

The clinical performance of the AlaSTAT Microplate Mixed Allergen Panels was demonstrated in the comparisons of the test results of the AlaSTAT Microplate Mixed Allergen Panels with the AlaSTAT Microplate Allergen-Specific IgE System.

Food Panel #5 (FP5M) vs. Specific Allergens (F1M, F2M, F3M, F4M, F13M, F14M)

		FP5M	
Specific Allergens	Pos	29	5
	Neg	0	29
		Pos	Neg

N	63
Agreement	92.1%
Rel. Sens.	85.3%
Rel. Spec.	100.0%

95% Confidence Limits for Relative Sensitivity and Specificity:
68.9% - 95.1% and 88.1% - 100%, respectively

Food Panel #6 (FP6M) vs. Specific Allergens (F4M, F9M, F10M, F11M, F14M)

		FP6M	
Specific Allergens	Pos	20	1
	Neg	0	13
		Pos	Neg

N	34
Agreement	97.1%
Rel. Sens.	95.2%
Rel. Spec.	100.0%

95% Confidence Limits for Relative Sensitivity and Specificity:
76.2% - 99.9% and 75.3% - 100%, respectively

Food Panel #7 (FP7M) vs. Specific Allergens (F1M, F2M, F4M, F9M, F13M, F14M)

		FP7M	
Specific Allergens	Pos	20	1
	Neg	0	15
		Pos	Neg

N	36
Agreement	97.2%
Rel. Sens.	95.2%
Rel. Spec.	100.0%

95% Confidence Limits for Relative Sensitivity and Specificity:
76.2% - 99.9% and 78.2% - 100%, respectively

Grass Panel #2 (GP2M) vs. Specific Allergens (G2M, G5M, G6M, G8M, G10M, G17M)

		GP2M			
				N	39
Specific	Pos	26	2	Agreement	94.9%
Allergens	Neg	0	11	Rel. Sens.	92.9%
		Pos	Neg	Rel. Spec.	100.0%

95% Confidence Limits for Relative Sensitivity and Specificity:
76.6% - 99.1% and 71.5% - 100%, respectively

Grass Panel #3 (GP3M) vs. Specific Allergens (G1M, G5M, G6M, G12M, G13M)

		GP3M			
				N	31
Specific	Pos	18	0	Agreement	96.8%
Allergens	Neg	1	12	Rel. Sens.	100.0%
		Pos	Neg	Rel. Spec.	92.3%

95% Confidence Limits for Relative Sensitivity and Specificity:
81.5% - 100% and 64% - 99.8%, respectively

Dust Panel #1 (HP1M) vs. Specific Allergens (H1M, D1M, D2M, I6M)

		HP1M			
				N	32
Specific	Pos	17	1	Agreement	96.9%
Allergens	Neg	0	14	Rel. Sens.	94.4%
		Pos	Neg	Rel. Spec.	100.0%

95% Confidence Limits for Relative Sensitivity and Specificity:
72.7% - 99.9% and 76.8% - 100%, respectively

The studies support the conclusion that the AlaSTAT Microplate Mixed Allergen Panels are as safe and effective as the predicate device.

Conclusion:

The information presented in this summary of safety and effectiveness is the information that the Food and Drug Administration used in granting DPC substantial equivalence for the AlaSTAT Microplate Mixed Allergen Panels.

Edward M. Levine, Ph.D.
Director of Clinical Affairs

11/4/98
Date

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

Edward M. Levine, Ph.D.
Director of Clinical Affairs
Diagnostic Products Corporation
5700 West 96th Street
Los Angeles, California 90045-5597

DEC 17 1998

Re: K983954
Trade Name: AlaSTAT Microplate Mixed Allergen Panels:
AlaSTAT Microplate Food Panel 5
AlaSTAT Microplate Food Panel 6
AlaSTAT Microplate Food Panel 7
AlaSTAT Microplate Dust Panel 1
AlaSTAT Microplate Grass Panel 2
AlaSTAT Microplate Grass Panel 3
Regulatory Class: II
Product Code: DHB
Dated: November 4, 1998
Received: November 5, 1998

Dear Dr. Levine:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we 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). 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 (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 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 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4588. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification"(21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597, or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Steven Gutman

Steven I. Gutman, M.D., M.B.A.
Director
Division of Clinical
Laboratory Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K983954

Device Name: **AlaSTAT Microplate Mixed Allergen Panels**

Indications For Use:

AlaSTAT Microplate Allergen-Specific IgE is a kinetic enzyme immunometric assay system designed for the measurement of allergen-specific IgE in serum. It is intended strictly for *in vitro* diagnostic use as an aid in the clinical diagnosis of IgE-mediated allergic disorders.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Peter E. Maxim

(Division Sign-Off)

Division of Clinical Laboratory Devices

510(k) Number K983954

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Prescription Use (Per 21 CFR 801.109) OR Over-The-Counter Use

(Optional Format 1-2-96)