

SEP 15 1998

K987343

Allergen ImmunoCAP™

510(k) Submission

Section 10. Summary of Safety and Effectiveness

10. 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.

Date of Summary Preparation: June 26, 1998

Distributor: Pharmacia & Upjohn
Diagnostics Division, US Operation
7425-248-1
7000 Portage Road
Kalamazoo, MI 49001

Manufacturer: Pharmacia & Upjohn, Diagnostics AB
S-751 82 Uppsala, Sweden
and
MIAB
Dragarbrunnsgatan 65
S-75320 Uppsala

Company Contact Person: Karen Matis
Regulatory Affairs Manager
Diagnostics Division
US Operation
7000 Portage Road
7425-248-01
Kalamazoo, MI 49001
(614) 794-3324 (Phone)
(614) 794-0266 (Fax)

Device Name: Allergen ImmunoCAP™ d73 (*Glycyphagus domesticus*)
Allergen ImmunoCAP™ d74 (*Euroglyphus maynei*)
Allergen ImmunoCAP™ e71 (Mouse Epithelium)
Allergen ImmunoCAP™ e72 (Mouse Urine)
Allergen ImmunoCAP™ e73 (Rat Epithelium)
Allergen ImmunoCAP™ e74 (Rat Urine)
Allergen ImmunoCAP™ e75 (Rat Serum Proteins)
Allergen ImmunoCAP™ e76 (Mouse Serum Proteins)
Allergen ImmunoCAP™ e87 (Rat)
Allergen ImmunoCAP™ e88 (Mouse)
Allergen ImmunoCAP™ f201 (Pecan Nut)
Allergen ImmunoCAP™ f215 (Lettuce)

Allergen ImmunoCAP™

510(k) Submission

Section 10. Summary of Safety and Effectiveness

Allergen ImmunoCAP™ f48 (Onion)
Allergen ImmunoCAP™ f90 (Malt)
Allergen ImmunoCAP™ f92 (Banana)
Allergen ImmunoCAP™ f96 (Avocado)
Allergen ImmunoCAP™ m70 (*Pityrosporum orbiculare*)
Allergen ImmunoCAP™ t17 (Japanese Cedar)
Allergen ImmunoCAP™ t72 (Queen Palm)
Allergen ImmunoCAP™ t73 (Australian Pine)

Common Name:

Allergen ImmunoCAP™ d73, d74, e71, e72, e73, e74, e75, e76, e87, e88, f48, f90, f92, f96, f201, f215, m70, t17, t72, t73
Solid phase components of immunological test system to measure allergen Specific IgE antibodies.

Classification:

<u>Product Name</u>	<u>Product Code</u>	<u>Class</u>	<u>CFR</u>
Allergen ImmunoCAP™ d73, d74, e71, e72, e73, e74, e75, e76, e87, e88, f48, f90, f92, f96, f201, f215, m70, t17, t72, t73	82 DHB	II	866.5750

Substantial Equivalence to:

AlaSTAT® Microplate Allergen Specific IgE, Specific Allergen Modules for d73, d74, e71, e72, e73, e74, e75, e76, e87, e88, f48, f90, f92, f96, f201, f215, m70, t17, t72, t73

Intended Use Statement :

Allergen ImmunoCAP™ is the solid phase component of the Pharmacia & Upjohn *in vitro* immunodiagnostic system, which measure specific IgE to the respective allergen, bound to the ImmunoCAP™. Allergen ImmunoCAP™ are intended to be used with Pharmacia CAP System™ RAST FEIA and UniCAP® Specific IgE *in vitro* diagnostic assays.

Allergen ImmunoCAP™ d73, d74, e71, e72, e73, e74, e75, e76, e87, e88, f48, f90, f92, f96, f201, f215, m70, t17, t72, t73 are included in this 510(k) submission.

Allergen ImmunoCAP™
510(k) Submission
Section 10. Summary of Safety and Effectiveness

General Description

Allergen ImmunoCAP™

The Allergen ImmunoCAP™ consists of a cellulose sponge matrix to which allergenic components are covalently coupled. The matrix is encased in a small round plastic capsule. This capsule is at the same time a holder of the matrix for convenient automation and a reaction chamber.

The sponge matrix is manufactured from activated cellulose derivative to which allergen extract solution is added under defined optimized conditions for the allergen coupling. This solid phase is an excellent carrier of allergens and provides favorable reaction conditions.

The Allergen ImmunoCAP™ contains allergens extracted from the different species and coupled to the individual Allergen ImmunoCAP™.

UniCAP®/Pharmacia CAP System™ RAST FEIA Specific IgE Test Principle

The allergen of interest, covalently coupled to ImmunoCAP, reacts with the specific IgE in the patient serum specimen. 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 response for the patient samples is compared directly to the response for the calibrators.

Device Comparison:

Pharmacia & Upjohn claims that results obtained with Pharmacia CAP System™ RAST® FEIA and UniCAP® Specific IgE for measuring Specific IgE against the allergens (Glycyphagus domesticus, Euroglyphus maynei, Mouse Epithelium, Mouse Urine, Rat Epithelium, Rat Urine, Rat Serum Proteins, Mouse Serum Proteins, Rat, Mouse, Pecan Nut, Lettuce, Onion, Malt, Banana, Avocado, Pityrosporum orbiculare, Japanese Cedar, Queen Palm, and Australian Pine) with the corresponding Allergen ImmunoCAP™ are substantially equivalent to results obtained with AlaSTAT® Microplate Allergen Specific IgE, Specific Allergen Modules for measuring Specific IgE for the same allergens.

Allergen ImmunoCAP™
510(k) Submission
Section 10. Summary of Safety and Effectiveness

Comparison Data:

A comparison study was performed in specific IgE testing using 20 single Allergens (see List of Allergens, Attachment 1). Data was generated with three assay systems Pharmacia & Upjohn Diagnostics products Pharmacia CAP System™ RAST® FEIA (PCS RAST), UniCAP® Specific IgE (UniCAP), and Diagnostic Products Corporation AlaSTAT® Microplate Allergen Specific IgE assay (AlaSTAT). Totally 524 tests with positive and negative sera were performed in all three assay systems. Comparison of specific IgE test results were performed between PCS RAST® vs. AlaSTAT® and UniCAP® vs. AlaSTAT®.

Agreement in positive and negative results between Pharmacia CAP System™ RAST® and AlaSTAT® was 80% –100 % for the single allergen and 93 % for all allergens. Complete agreement within Classes \pm 1 Class was 83 % for all allergens. The relative sensitivity and specificity for Pharmacia CAP System™ RAST® vs. AlaSTAT® was 98% and 77 % respectively.

Agreement in positive and negative results between UniCAP® and AlaSTAT® was 75% –100 % for the single allergen and 93 % for all allergens. Complete agreement within Classes \pm 1 Class was 84 % for all allergens. The relative sensitivity and specificity for UniCAP® vs. AlaSTAT® was equally 98% and 77% respectively.

This study demonstrates that the specified Allergen ImmunoCAP™ tested in Pharmacia CAP System™ RAST® FEIA and UniCAP® Specific IgE are substantially equivalent to the legally marketed predicate device AlaSTAT® Microplate Allergen Specific IgE Specific Allergen Modules for corresponding allergens.

Allergen ImmunoCAP™
510(k) Submission
Section 10. Summary of Safety and Effectiveness

Attachment 1

LIST OF ALLERGENS

#	Code	Allergen
1	d73	Glycyphagus domesticus
2	d74	Euroglyphus maynei
3	e71	Mouse Epithelium
4	e72	Mouse Urine
5	e73	Rat Epithelium
6	e74	Rat Urine
7	e75	Rat Serum Proteins
8	e76	Mouse Serum Proteins
9	e87	Rat
10	e88	Mouse .
11	f201	Pecan Nut
12	f215	Lettuce
13	f48	Onion
14	f90	Malt
15	f92	Banana
16	f96	Avocado
17	m70	Pityrosporum orbiculare
18	t17	Japanese Cedar
19	t72	Queen Palm
20	t73	Australian Pine



SEP 15 1998

Ms. Karen Matis
Regulatory Affairs Manager
Pharmacia & Upjohn
Diagnostics Division/US Operation
7000 Portage Road, 7425-248-01
Kalamazoo, Michigan 49001

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

Re: K982343

Trade Name: Allergen ImmunoCAP™ d73, d74, e71, 372, e73, e74,
e75, e76, e87, e88, f48, f90, f92, f96, f201, f215,
m70, t17, t72, t73

Regulatory Class: II

Product Code: DHB

Dated: July 2, 1998

Received: July 6, 1998

Dear Ms. Matis:

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.

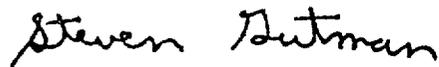
If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially 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.

Page 2

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

Enclosure

Allergen ImmunoCAP™
510(k) Submission
Section 1. Intended Use Statement

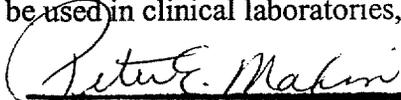
510(k) Number (if known): K982343

Device Names: Allergen ImmunoCAP™

d73 *Glycyphagus domesticus*, d74 *Euroglyphus maynei*, e71 Mouse epithelium, e72 Mouse urine proteins, e73 Rat epithelium, e74 Rat urine proteins, e75 Rat serum proteins, e76 Mouse serum proteins, e87 Rat, e88 Mouse, f48 Onion, f90 Malt, f92 Banana, f96 Avocado, f201 Pecannut, f215 Lettuce, m70 *Pityrosprum orbiculare*, t17 Japanese Cedar, t72 *Arecastrum Romanzoffianum*, t73 *Casaurina Equisetifolia*

Allergen ImmunoCAP™ is the solid phase component of the Pharmacia & Upjohn in vitro immunodiagnostic systems which measure specific IgE to the respective allergen bound to the ImmunoCAP. Allergen ImmunoCAP are intended to be used with Pharmacia CAP System RAST FEIA and UniCAP Specific IgE in vitro diagnostic assays.

Pharmacia CAP System RAST FEIA and UniCAP Specific IgE are intended for in vitro diagnostic use as an aid in the clinical diagnosis of IgE mediated allergic disorders in conjunction with other findings, and are to be used in clinical laboratories, as well as, physician office laboratories.


(Division Sign-Off)
Division of Clinical Laboratory Devices
510(k) Number K982343

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use OR Over-The-Counter Use

(Per 21 CFR 801.109)