

Allergen ImmunoCAP™
510(k) Submission
Section 7. Summary of Safety and Effectiveness

FEB - 9 1998

7. 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: November 25, 1997

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

Manufacturer: Pharmacia & Upjohn, Diagnostics AB
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and
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Component Name: Allergen ImmunoCAP™ f256 Walnut
Allergen ImmunoCAP™ f245 Whole Egg
Allergen ImmunoCAP™ f207 Clam
Allergen ImmunoCAP™ f202 Cashew Nut

Common Name: Allergen ImmunoCAP™
Solid phase components of immunological
test systems to measure allergen Specific IgE
antibodies.

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Classification:

<u>Product Name</u>	<u>Product Code</u>	<u>Class</u>	<u>CFR</u>
Allergen ImmunoCAP™ f256, f245, f207, f202	82 DHB	II	866.5750

Predicate Test Systems For The Measurement of Specific IgE

Pharmacia CAP System™ RAST FEIA	K894190, K911903
UniCAP™ Specific IgE Assay	K962274

Intended Use Statement :

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.

Allergen ImmunoCAP™ f256 Walnut, f245 Whole Egg, f207 Clam, f202 Cashew Nut are included in this 510(k) submission.

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.

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UniCAP™ Specific IgE and Pharmacia CAP System™ RAST FEIA Specific IgE Test Principle

The allergen of interest (Walnut, Whole Egg, Clam or Cashew Nut), covalently coupled to ImmunoCAP™, reacts with the specific IgE in the patient serum specimen. After washing away non-specific IgE, enzyme labelled 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.

Performance Characteristics Of Allergen ImmunoCAP™

The safety and effectiveness of the test systems Pharmacia CAP System™ RAST FEIA and UniCAP™ Specific IgE for the determination of specific IgE antibodies have been established in previous 510(k) submissions. This 510(k) submission includes data to add four additional Allergen ImmunoCAP™ to the Pharmacia CAP System™ and UniCAP™ test systems for the measurement of specific IgE.

RAST inhibition verifies the immunological specificity of IgE binding for each allergen. The function of the Allergen ImmunoCAP™ is further verified by testing clinical serum samples, with a history or indication of allergy to the specific allergen, and established negative samples. The analysis was performed in both Pharmacia CAP System™ and UniCAP™ test systems and results show a complete agreement of outcome concerning positive and negative samples in both systems.

The importance of each allergen is demonstrated with relevant literature references covering frequency, clinical use and description of related allergens. Reproducibility between production lots and stability studies complete the picture by showing the constant quality of the Allergen ImmunoCAP™.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Ms. Karen Matis
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FEB - 9 1998

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

Re: K974580
Trade Name: Allergen ImmunoCAP™ f256, f245, f207, f202
Regulatory Class: II
Product Code: DHB
Dated: December 4, 1997
Received: December 8, 1997

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 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 (Pre-market 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 requirement, 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.

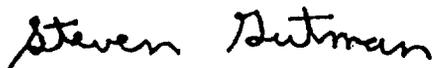
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Under the Clinical Laboratory Improvement Amendments of 1988 (CLIA-88), this device may require a CLIA complexity categorization. To determine if it does, you should contact the Centers for Disease Control and Prevention (CDC) at (770)488-7655.

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 at (301) 443-6597 or at its internet address "<http://www.fda.gov/cdrh/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

