K974350

FEB - 9 1998

Classification:

Product Name	Product Code	Class	CFR
Allergen ImmunoCAP™ m4, m8 and k70	82 DHB	II	866.5750

Substantial Equivalence to:

Phadebas RAST® Allergen Discs m4 *Mucor racemosus*, m8 *Helminthosporium halodes* and k70 Green Coffee Bean used with Phadebas RAST® immunodiagnostic test system.

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™ m4 (*Mucor racemosus*), m8 (*Helminthosporium halodes*) and k70 (Green Coffee Bean) 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 tha 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™ m4 contains allergens from the mold *Mucor racemosus*, Allergen ImmunoCAP™ m8 from *Helminthosporium halodes* (both

spores and mycelium). Identical sources and extracts are used for both the predicate device Phadebas RAST Paper Disc and ImmunoCAP™.

The Allergen ImmunoCAP™ k70 contains allergens extracted from the Green Coffee Bean. Identical source and extract is also used for both the predicate device Phadebas RAST Paper Disc and ImmunoCAP™.

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

The allergen of interest (*Mucor racemosus*, *Helminthosporium halodes* or Green Coffee Bean), 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.

Device Comparison:

Pharmacia & Upjohn claims that results obtained with UniCAP™ Specific IgE and Pharmacia CAP System™ RAST FEIA for measuring Specific IgE against the allergens *Mucor racemosus* (m4), *Helminthosporium halodes* (m8) and Green Coffee Bean (k70) with the Allergen ImmunoCAP ™ are substantially equivalent to results obtained with Phadebas RAST® Allergens Paper Discs measuring Specific IgE for the same allergens.

Comparison Data:

Comparison studies were performed comparing specific IgE results obtained from 3 test systems. IgE results from the predicate device, Phadebas RAST® using allergen paper disc technology were compared to IgE results obtained using the new technology Allergen ImmunoCAP™ where allergens are bound to a three dimesional cellulose sponge. The three new ImmunoCAP™ allergens (m4, m8, k70) were evaluated using the test systems Pharmacia CAP System™ and UniCAP™. Positive and negative sera from patients with and without specific IgE to each of the three allergens have been tested in all three test systems. Results for the correlation between the methods is presented as comparison between

Pharmacia CAP System™ vs Phadebas RAST®and UniCAP™ vs Phadebas RAST®respectively and calculated as:

1) Percent agreement in positive and negative results in the test systems compared.

2) Complete percent agreement within Classes ± 1 Class in the test systems.

Agreement in positive and negative results between Phadebas RAST®and Pharmacia CAP System™ was 85 % for Allergen m4, and 95 % for allergens m8 and k70 . Complete agreement within Classes ± 1 Class was 83 % for m4, 98 % for m8 and 95 % for k70.

Agreement in positive and negative results between Phadebas RAST®and UniCAP™ was 85 % for allergen m4, and 95 % for allergens m8 and k70. The complete agreement within Classes ± 1 Class was 80% for m4, 95 % for m8 and 95 % for k70.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

FEB - 9 1998

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

Re: K974350
Trade Name: Allergen ImmunoCAP™ m4, m8 and k70
Regulatory Class: II
Product Code: DHB
Dated: November 18, 1997
Received: November 19, 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 (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 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.

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 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

Allergen ImmunoCAP™ m4, m8, k70
510(k) Submission
Section 1. Intended Use Statement

510(k) Number (if known): K974350

Device Name: Allergen ImmunoCAP™ m4 - Mucor racemosus
Allergen ImmunoCAP™ m8- Helminthosporium halodes
Allergen ImmunoCAP™ k70- Green Coffee Bean

Indications For Use:

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.

It is intended for in vitro diagnostic use as an aid in the clinical diagnosis of IgE mediated allergic disorders in conjunction with other findings, and is to be used in clinical laboratories, as well as, physician office laboratories.

(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)

Peter E. Maxim
(Division Sign-Off)
Division of Clinical Laboratory Devices
510(k) Number K974350