

JUL - 3 1997

UniCAP Specific IgE, Latex Allergen ImmunoCAP k82  
510(k) Submission  
Section 9. Summary of Safety and Effectiveness

K972068

9. 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:** May 15, 1997

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

**Manufacturer:** Pharmacia & Upjohn Diagnostics  
S-751 82 Uppsala, Sweden

**Company Contact Person:** Karen E. Matis  
Regulatory Affairs Manager  
Diagnostics Division  
US Operations  
7000 Portage Rd.  
Kalamazoo, MI 49001  
7425-248-1  
(614) 794-3324 (Phone)  
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**Device Name:** UniCAP Specific IgE FEIA Assay  
Latex Allergen ImmunoCAP k82

**Common Name:** Fluorescence Enzyme Immunoassay  
for the detection of specific IgE antibodies to latex

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**Classification:**

<u>Product Name</u>	<u>Product Code</u>	<u>Class</u>	<u>CFR</u>
UniCAP Specific IgE Assay, Latex Allergen ImmunoCAP k82	82 DHB	II	866.5750

**Substantial Equivalence to:**

Pharmacia CAP System RAST<sup>®</sup> FEIA  
Latex Allergen ImmunoCAP k82 510(k) K962976.

**Intended Use Statement:**

UniCAP Specific IgE Assay is an in vitro semi-quantitative assay for the measurement of allergen specific IgE in human serum or plasma. UniCAP Specific IgE Assay is to be used with the instrument UniCAP 100. It is intended for in vitro diagnostic use as an aid in the clinical diagnosis of IgE mediated allergic disorders in conjunction with other clinical findings, and is to be used in clinical laboratories, as well as, physician office laboratories

**Information Specific to Latex k82 Allergen**

UniCAP Specific IgE Assay, Latex k82 test results may be used as an aid in the clinical diagnosis of patients with suspected latex allergy.

**General Description**

Since 1967, when the first assays for serum immunoglobulin E and allergen-specific IgE antibodies in serum were described, these measurements have become well established components of the investigation of allergic patients. UniCAP Specific IgE FEIA is an in vitro test system, based on ImmunoCAP technology, for the determination of circulating specific IgE antibodies.

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**Description of the Device**

The allergen of interest, in this case Latex, 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 greater the quantity of specific IgE present in the specimen. To evaluate the test results, the response for the patient sample is compared directly to the response for the calibrators.

UniCAP 100 instrument with built in software processes all steps of the assay and prints results automatically after the assay is completed.

**Latex Specific Performance Characteristics**

**Summary of Comparison Study**

Serum samples from a total of 182 patients from three clinical sites were tested by UniCAP Specific IgE FEIA Latex Allergen ImmunoCAP k82. Ninety-six (96) of these patients were diagnosed as clinically allergic to latex and had a positive latex skin test, while the remaining eighty-six (86) patients were clinically negative and had negative latex skin test. All samples were also tested in parallel by Pharmacia CAP System RAST<sup>®</sup> FEIA the predicate 510(K) cleared, commercially available latex specific IgE assay.

The Comparison Study data show that determination of specific IgE to latex with UniCAP Specific IgE FEIA has an excellent clinical performance and is substantially equivalent to Pharmacia CAP System RAST FEIA, the legally marketed predicate device.

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Table 1. Clinical Sensitivity and Specificity For Comparison Study Between Two Specific IgE Assay Systems (UniCAP Specific IgE FEIA Assay and Pharmacia CAP System RAST FEIA) vs. Clinical Diagnosis of Latex Sensitivity.

N = 182

<u>Clinical Diagnosis<sup>ab</sup> /SPT</u>	UniCAP Specific IgE FEIA Latex-Specific Assay (Latex Allergen ImmunoCAP k82)				Pharmacia CAP System RAST FEIA Latex-Specific Assay (Latex Allergen ImmunoCAP k82)			
	Pos	Neg	Clinical Sensitivity	Clinical Specificity	Pos	Neg	Clinical Sensitivity	Clinical Specificity
Positive	70	26	72.9%		71	25	73.9%	
Negative	1	85		98.8%	1	85		98.8%
	Overall Agreement*: 85.1 %				Overall Agreement*: 85.7 %			

a = Clinical Diagnosis as defined by clinical history and latex skin test (SPT) results

b = Data on file at Pharmacia & Upjohn

\* = Overall Agreement is defined as concordance between all positive and negative in vitro test results with clinical diagnosis.



Food and Drug Administration  
2098 Gaither Road  
Rockville MD 20850

Karen E. Mathis  
Manager, Regulatory Affairs  
PHARMACIA & UPJOHN  
5094 St. Andrew Drive  
Westerville, OH 43082

JUL - 3 1997

Re: K972068  
Trade Name: UniCAP Specific IgE FEIA Assay, Latex Allergen ImmuoCAP k82  
Regulatory Class: II  
Product Code: DHB  
Dated: June 02, 1997  
Received: June 03, 1997

Dear Ms. Mathis:

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 Good Manufacturing Practice for Medical Devices: General (GMP) regulation (21 CFR Part 820) and that, through periodic GMP 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.

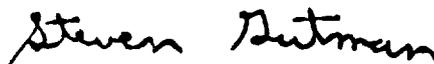
Under the Clinical Laboratory Improvement Amendments of 1988 (CLIA-88), this device may require a CLIA complexity categorization. To determine if it does, you should contact the Centers for Disease Control and Prevention (CDC) at (770)488-7655.

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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

