

11. **SUMMARY OF SAFETY AND EFFECTIVENESS**

This summary of safety and effectiveness information is being submitted in accordance with the requirements of The Safe Medical Devices Act of 1990 (SMDA 1990).

**Date of Summary Preparation:** June 19, 1997

**Distributor:** Pharmacia & Upjohn  
Diagnostics Division  
US Operations

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

**Company Contact Person:** Karen E. Matis  
Regulatory Affairs Manager  
Pharmacia & Upjohn  
Diagnostics Division  
US Operations  
7000 Portage Road  
7425-248-1  
Kalamazoo, MI 49001-0199

**Device Name:** UniCAP Phadiatop Assay

**Common Name:** *In vitro* assay for the qualitative differential determination of IgE antibodies to inhalant allergens.

**Classification:**

<u>Product Name</u>	<u>Product Code</u>	<u>Class</u>	<u>CFR</u>
UniCAP Phadiatop Assay	82DHB	II	866.5750

**Substantial Equivalence to:**

Pharmacia CAP System Phadiatop

**UniCAP Phadiatop  
510(k) Submission  
Section 11. Summary of Safety and Effectiveness**

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**Intended Use Statement:**

UniCAP Phadiatop Assay is an in vitro qualitative assay for the differential determination of IgE antibodies specific to inhalant allergens in human serum and plasma. UniCAP Phadiatop 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 findings, and is to be used in clinical laboratories, as well as, physician office laboratories.

**General Description:**

UniCAP is a fully integrated and automated system for the determination of total and specific IgE in human serum or plasma. The UniCAP system includes the UniCAP 100 instrument with software for immunodiagnostic testing; UniCAP RM External Software; UniCAP reagents, in this submission reagents for the differential determination of IgE antibodies specific to inhalant allergens.

**Device Comparison:**

UniCAP Phadiatop Assay reagents when used with the UniCAP 100 Instrument are substantially equivalent to another commercially available assay and instrumentation system for the differential determination of IgE antibodies specific to inhalant allergens, namely Pharmacia CAP System Phadiatop FEIA used with Pharmacia CAP System instrumentation.

**Comparison Data:**

Comparison studies were performed to establish the substantial equivalence of results using UniCAP 100 and UniCAP Phadiatop Assay compared to the corresponding instrumentation and reagents in Pharmacia CAP System.

The comparison study comprised 150 positive serum samples with specificities to all inhalant allergens coupled to the Phadiatop Sample ImmunoCAP. In addition, 30 negative serum samples chosen in the same way were assayed. The results, recorded as positive or negative, showed 100% agreement.

Therefore, Pharmacia & Upjohn Diagnostics concludes that the two in vitro diagnostic assay systems show excellent correlation, and are substantially equivalent.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

SEP - 4 1997

Food and Drug Administration  
2098 Gaither Road  
Rockville MD 20850

Ms. Karen E. Matis  
Regulatory Affairs Manager  
Diagnostics Division  
Pharmacia & Upjohn  
7000 Portage Road  
7425-248-1  
Kalamazoo, Michigan 49001-0199

Re: K972364  
Trade Name: UniCAP Phadiatop Assay®  
Regulatory Class: II  
Product Code: DHB  
Dated: June 24, 1997  
Received: June 25, 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.

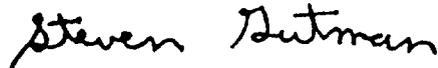
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Under the Clinical Laboratory Improvement Amendments of 1988 (CLIA-88), this device may require a CLIA complexity categorization. To determine if it does, you should contact the Centers for Disease Control and Prevention (CDC) at (770)488-7655.

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

**UniCAP Phadiatop  
510(k) Submission  
Section 1. Intended Use Statement**

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510(k) Number (if known): \_\_\_\_\_

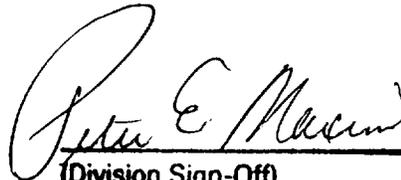
Device Name: \_\_\_\_\_ UniCAP Phadiatop Assay \_\_\_\_\_

Indications For Use: \_\_\_\_\_

UniCAP Phadiatop Assay is an in vitro qualitative assay for the differential determination of IgE antibodies specific to inhalant allergens in human serum and plasma. UniCAP Phadiatop 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 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)



(Division Sign-Off)

Division of Clinical Laboratory Devices

510(k) Number \_\_\_\_\_

Prescription Use  \_\_\_\_\_

OR

Over-The-Counter Use \_\_\_\_\_

(Per 21 CFR 801.109)