

7/28/99

**Pharmacia CAP System IgE FEIA Modified Device 510(k) Submission
Section 10. Summary of Safety and Effectiveness**

K991945

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: May 31, 1999

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

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: Pharmacia CAP System IgE FEIA

Common Name: *In vitro* quantitative assay for the measurement of circulating total IgE.

Classification:

<u>Product Name</u>	<u>Product Code</u>	<u>Class</u>	<u>CFR</u>
Pharmacia CAP System IgE FEIA	82 DGC	II	866.5510

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Substantial Equivalence to:

Pharmacia CAP System IgE FEIA

Intended Use Statement:

Pharmacia CAP System IgE FEIA is an in vitro test system for the quantitative measurement of circulating total IgE antibodies in human blood samples.

General Description

Reagent Description

Pharmacia CAP System IgE FEIA contains three separate units: IgE FEIA Fluoroenzymeimmuno reagents, IgE FEIA Standard reagents and Anti-IgE FEIA ImmunoCAP. The expiry date for the complete packages are stated on the outer labels and the recommended storage temperature is +2-8°C. However, each component is stable until the date stated on the respective label.

Device Modification Description

The product update (Pharmacia CAP System IgE FEIA) consists of a modification of the antibodies in the Enzyme-Anti-IgE and Anti-IgE ImmunoCAP reagents.

In **Enzyme-Anti-IgE Modification**: From a mix of rabbit antiserum/mouse monoclonal to only mouse monoclonal antibodies.

In **Anti-IgE ImmunoCAP Modification**: From Antiserum raised in sheep to mouse monoclonal. All other reagents remain unchanged.

This modification makes it possible to use an alternative, more rapid procedure with the same reagents: The 2nd Incubation (reaction with Enzyme-Anti-IgE) time can be shortened to 30 min (the "TEMPO procedure") or the standard incubation time of 150 min can be utilized (Standard Procedure). Other test parameters remain unchanged.

Pharmacia CAP System™ IgE FEIA, Test Principle

Anti-IgE, covalently coupled to ImmunoCAP, reacts with the total IgE in the patient serum specimen. After washing, 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 in FluoroCount 96. The fluorescence is directly proportional to the concentration of IgE in the blood sample.

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Device Comparison:

The purpose of the comparison study was to show that the modified Pharmacia CAP System IgE FEIA gives concordant results compared to the predicate device, Pharmacia CAP System IgE FEIA using both the "Standard" procedure and a more rapid procedure (the "TEMPO" procedure). A sample population of 106 patient samples with varying contents of IgE antibodies was included in the study.

Comparison Data results:

93 % of the samples tested in the updated product (Standard procedure) had a result within ± 15 % of the result obtained with the predicate Pharmacia CAP System IgE FEIA. 88 % of the samples tested utilizing the TEMPO procedure had results within ± 15 % the predicate Pharmacia CAP System IgE FEIA.

This study demonstrates that the "updated" Pharmacia CAP System IgE FEIA using both the "Standard FEIA" and the "TEMPO" procedures gives substantially equivalent results compared to the the predicate Pharmacia CAP System IgE FEIA product.



DEPARTMENT OF HEALTH & HUMAN SERVICES

JUL 28 1999

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

Ms. Karen Matis
Manager, Regulatory Affairs and
Quality Management
Diagnostics Division, US Operations
Pharmacia & Upjohn
7000 Portage Road
7425-248-01
Kalamazoo, Michigan 49001-0199

Re: K991945
Trade Name: Pharmacia CAP System IgE FEIA
Regulatory Class: II
Product Code: DGC
Dated: June 8, 1999
Received: June 9, 1999

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.

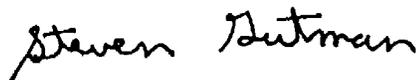
Page 2

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

Sincerely yours,



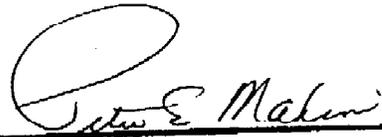
Steven I. Gutman, M.D, M.B.A.
Director
Division of Clinical
Laboratory Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Pharmacia CAP System IgE FEIA Modified Device 510(k) Submission
510(k) Submission
Section 1. Intended Use Statement

510(k) Number (if known): K991945

Device Name: **Pharmacia CAP System IgE FEIA** is an in vitro test system for the quantitative measurement of circulating total IgE in human blood samples.



(Division Sign-Off)
Division of Clinical Laboratory Devices
510(k) Number K991945

(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)