K981930 ✓

11. 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: June 23, 1998

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 E. Matis
Regulatory Affairs Manager
Diagnostics Division
US Operation
7000 Portage Road
7425-248-01
Kalamazoo, MI 49001
(614) 794-3324 (Phone)
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Device Names:
UniCAP® Thyroglubulin IgG Assay
UniCAP® Thyroid Peroxidase IgG Assay
UniCAP® Thyroglobulin IgG Antibodies Control NLH
UniCAP® Thyroid Peroxidase IgG Antibodies Control NLH

Common Name: Thyroid autoantibody immunological test system.

Classification:

Product Name	Product Code	Class	CFR
UniCAP® Thyroglobulin IgG Assay	82JNL	II	866.5870
UniCAP Thyroid Peroxidase IgG Assay	82JZO	II	866.5870
UniCAP Thyroglobulin IgG Antibodies Control NLH	82JNL	II	866.5870
UniCAP Thyroid Peroxidase IgG Antibodies Control NLH	82JZO	II	866.5870

Substantial Equivalence to:

Varelisa® Thyroglobulin Antibodies Assay
Varelisa Thyroid Peroxidase Antibodies Assay

Intended Use Statement :

UniCAP Thyroglobulin ImmunoCAP™ is a device for the in vitro quantitative measurement of IgG antibodies specific for Thyroglobulin (TG) in human serum and plasma. UniCAP Thyroglobulin ImmunoCAP is intended to be used with the instrument UniCAP together with reagents as stated in the Directions For Use provided with UniCAP Specific IgG. It is intended for in vitro diagnostic use as an aid in the clinical diagnosis of certain thyroid diseases, such as autoimmune thyroiditis and Graves' Disease and is to be used in clinical laboratories, as well as, physician office laboratories.

UniCAP Thyroid Peroxidase ImmunoCAP is a device for the in vitro quantitative measurement of IgG antibodies specific for Thyroid Peroxidase (TPO) in human serum and plasma. UniCAP Thyroid Peroxidase ImmunoCAP is intended to be used with the instrument UniCAP together with reagents as stated in the Directions For Use provided with UniCAP Specific IgG. It is intended for in vitro diagnostic use as an aid in the clinical diagnosis of certain thyroid diseases, such as autoimmune thyroiditis, and Graves' Disease and is to be used in clinical laboratories, as well as, physician office laboratories.

UniCAP® Specific IgG is an in vitro test system for the quantitative and qualitative measurement of antigen specific IgG antibodies. The corresponding antigen for the specific antibody to be measured by UniCAP Specific IgG is bound to the Antigen ImmunoCAP™ solid phase component of the UniCAP Specific IgG System. UniCAP Specific IgG assay is to be used with the instrument UniCAP. It is intended for in vitro diagnostic use in conjunction with other clinical findings, and is to be used in clinical laboratories, as well as physician office laboratories.

UniCAP Thyroglobulin IgG Antibodies Controls are intended for laboratory use in monitoring the performance of in vitro quantitative measurement of IgG antibodies specific for Thyroglobulin in human serum. UniCAP Thyroglobulin IgG Antibodies Controls are intended to be used with the instrument UniCAP.

UniCAP Thyroid Peroxidase IgG Antibodies Controls are intended for laboratory use in monitoring the performance of in vitro quantitative measurement of IgG antibodies specific for Thyroid Peroxidase in human serum. UniCAP Thyroid Peroxidase IgG Antibodies Controls are intended to be used with the instrument UniCAP.

General Description

UniCAP Immunodiagnostic System is a fully integrated and automated system for immunodiagnostic testing. UniCAP System is comprised of Instruments (UniCAP 100 Analyzer, Test System Modules and Assay Products (Fluororenzymeimmunoassays for the measurement of IgE, IgG), ImmunoCAP™ Antigens (solid phase components which contain the specific antigens to be measured), and Software Accessories.

UniCAP 100 Analyzer is designed to handle all steps from sample and reagents handling to processing of results. Reagents, requests, samples and ImmunoCAP are loaded into the instrument and the process, which takes 2.5 hours is started. A laboratory report is automatically printed when the process is ended.

UniCAP 100 can store a calibration curve to be used for up to one month. After an initial calibration curve is accepted by the software, subsequent assay runs may use the stored calibration curve for calculation of results. In these runs, Curve Controls are included to validate that the run is on the same response level as the stored curve. Limits for the response of the Curve Controls are defined in the UniCAP 100 Operator and Panel Software.

UniCAP® 100 RM External Software is intended to be used with a Windows-based PC operating up to five UniCAP 100 instruments. The external software creates requests and assay runs, retrieves the test results from the instrument, and prints reports. It can also import requests from, and export requests to, a connected mainframe computer or network server.

UniCAP Specific IgG is a fluoroenzymeimmunoassay for the quantitative measurement of antigen specific IgG antibodies. The corresponding antigen for the specific antibody to be measured by UniCAP Specific IgG is bound to the Antigen ImmunoCAP™ solid phase component. Specific IgG antibodies in the patient serum or plasma specimen react with the antigens of interest, in this submission, Thyroglobulin and Thyroid Peroxidase, which are covalently coupled to ImmunoCAP.

The UniCAP Thyroid Peroxidase ImmunoCAP contains recombinant human Thyroid Peroxidase covalently coupled to a cellulose matrix. The UniCAP Thyroglobulin ImmunoCAP contains purified human Thyroglobulin covalently coupled to the cellulose matrix.

Comparison Data:

UniCAP Thyroglobulin IgG Assay

A comparison study was performend to generate correlation data between UniCAP Thyroglobulin IgG Assay and Varelisa® TG Antibody Assay. This study was performed to demonstrate that the performance of UniCAP Thyroglobulin IgG Assay is substantially equivalent to Varelisa TG Antibody Assay, which is the legally marketed predicate device in the United States. 100 serum samples were collected and were run on both assay systems with the following results.

Linear regression analysis gave the equation:

$Y = 1.04 * X + 11$ with correlation coefficient 0.99

This correlation study demonstrated that the new device, UniCAP Thyroglobulin IgG Assay is substantially equivalent to the legally marketed predicate device, Varelisa Thyroglobulin Antibodies Assay.

UniCAP® Thyroid Peroxidase IgG Assay

A comparison study was performed to generate correlation data between UniCAP Thyroid Peroxidase IgG Assay and Varelisa® TPO Antibody Assay. This study was performed to demonstrate that the performance of UniCAP Thyroid Peroxidase IgG Assay is substantially equivalent to Varelisa TPO Antibody Assay, which is the legally marketed predicate device in the United States. 100 serum samples were collected and were run on both assay systems with the following results.

Linear regression analysis gave the following equation:

$Y = 1.04 * X$ with correlation coefficient 0.99

This correlation study demonstrated that the new device, UniCAP Thyroid Peroxidase IgG Assay is substantially equivalent to the legally marketed predicate device, Varelisa Thyroid Peroxidase Antibodies Assay.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

JUL 7 1998

Ms. Karen E. Matis
Regulatory Affairs Manager
Pharmacia & Upjohn
Diagnostics Division, US Operations
5084 St. Andrews Drive
Westerville, Ohio 43082

Re: K981930
Trade Name: UniCAP® Thyroid Peroxidase IgG Assay
Regulatory Class: II
Product Code: JZO
Dated: April 30, 1998
Received: May 1, 1998

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

UniCAP® Thyroglobulin IgG Assay/ UniCAP® Thyroid Peroxidase IgG Assay
510(k) Submission
Section 1. Intended Use Statements

510(k) Number (if known): K981930

Device Name: **UniCAP® Thyroid Peroxidase IgG Assay**

Indications For Use: UniCAP Thyroid Peroxidase ImmunoCAP™ is a device for the in vitro quantitative measurement of IgG antibodies specific for Thyroid Peroxidase (TPO) in human serum and plasma. UniCAP Thyroid Peroxidase ImmunoCAP is intended to be used with the instrument UniCAP together with reagents as stated in the Directions For Use provided with UniCAP Specific IgG. It is intended for in vitro diagnostic use as an aid in the clinical diagnosis of certain thyroid diseases, such as autoimmune thyroiditis and Graves' Disease and is to be used in clinical laboratories, as well as, physician office laboratories.

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(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Peter E Magnus

(Division Sign-Off)
Division of Clinical Laboratory Devices
510(k) Number K981930

Prescription Use ✓ OR Over-The-Counter Use _____
(Per 21 CFR 801.109)