OCT 22 1998

K982533 ✓
K982701

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: July 13, 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 Name:
UniCAP® Gliadin IgA Assay
UniCAP® Gliadin IgG Assay

Common Name: Antibodies, Gliadin

Classification:

Product Name	**Product Code**	**Class**	**CFR**
UniCAP® Gliadin IgA Assay	82 MST	II	866.5750
UniCAP® Gliadin IgG Assay	82 MST	II	866.5750

Substantial Equivalence to:
ImmuLisa™ IgA Anti-Gliadin Antibody K982533 ✓
ImmuLisa™ IgG Anti-Gliadin Antibody K982701

Intended Use Statements:

IgA	IgG
UniCAP Gliadin IgA/IgG ImmunoCAP™ is a device for the in vitro semi-quantitative measurement of IgA or IgG antibodies specific for gliadin in human serum. UniCAP Gliadin IgA/IgG ImmunoCAP is intended to be used with the instrument UniCAP together with reagents as stated in the Directions for Use provided with UniCAP Specific IgA. It is intended for in vitro diagnostic use as an aid in the diagnosis of patients with celiac disease.	UniCAP Gliadin IgA/IgG ImmunoCAP™ is a device for the in vitro semi-quantitative measurement of IgA or IgG antibodies specific for gliadin in human serum. UniCAP Gliadin IgA/IgG 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 diagnosis of patients with celiac disease.
UniCAP Specific IgA is an in vitro test system for the quantitative measurement of antigen specific IgA antibodies. The corresponding antigen for the specific antibody to be measured by UniCAP Specific IgA is bound to the Antigen ImmunoCAP solid phase component of the UniCAP Specific IgA system. UniCAP Specific IgA 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 Specific IgG is an in vitro test system 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 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.

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

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, Gliadin, which are covalently coupled to ImmunoCAP.

Comparison Data:

A comparison study was performed between UniCAP® Gliadin IgA Assay and Immco® Diagnostics ImmuLisa™ Anti-Gliadin IgA Antibody (AGA) ELISA, and UniCAP® Gliadin IgG Assay and Immco® Diagnostics ImmuLisa™ Anti-Gliadin IgG Antibody (AGA) ELISA. The study was performed to demonstrate that the performance of UniCAP® Gliadin IgA/IgG FEIA Assays are substantially equivalent to ImmuLisa™ Anti-Gliadin (IgA and IgG) Antibody (AGA) ELISA assays respectively. ImmuLisa™ Anti-Gliadin IgA and IgG Antibody ELISA are the legally marketed predicate devices in the United States.

Ninety-eight (98) IgA and 99 IgG positive and negative serum samples were collected and run in both assay systems. The reported serum concentration in mg_A/l and EU/ml values were obtained in diluted samples corrected for serum

dilution. All serum samples were analyzed in duplicate in three assays for each system.

The results of UniCAP® Gliadin IgA FEIA and ImmuLisa™ Anti-Gliadin IgA Antibody (AGA) ELISA were compared by determining the total agreement (in %) of positive and negative test results between the two tests. The total agreement between the two tests was calculated to be 72 %.

Similarly the results of UniCAP® Gliadin IgG FEIA and ImmuLisa™ Anti-Gliadin IgG Antibody (AGA) ELISA were compared by determining the total agreement (in %) in positive and negative test results between the two tests. The total agreement between these tests was calculated to be 81 %.

This study demonstrates that the new devices Pharmacia &Upjohn UniCAP® Gliadin IgA Assay and UniCAP® Gliadin IgG Assay are substantially equivalent to Immco ImmuLisa™ Anti-Gliadin (IgA and IgG) Antibody (AGA) ELISA.

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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

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

Re: K982533/S1
Trade Name: UniCAP® Gliadin IgA Assay
Regulatory Class: II
Product Code: MST
Dated: September 22, 1998
Received: September 24, 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 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.

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 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® Gliadin IgA Assay and UniCAP Gliadin IgG Assay
510(k) Submission
Section 1. Intended Use Statement

510(k) Number K982533 ✓ K982701

Device Name: **UniCAP® Gliadin IgA Assay and UniCAP Gliadin IgG Assay**

IgA

UniCAP Gliadin IgA/IgG ImmunoCAP™ is a device for the in vitro semi-quantitative measurement of IgA or IgG antibodies specific for gliadin in human serum. UniCAP Gliadin IgA/IgG ImmunoCAP is intended to be used with the instrument UniCAP together with reagents as stated in the Directions for Use provided with UniCAP Specific IgA. It is intended for in vitro diagnostic use as an aid in the diagnosis of patients with celiac disease.

UniCAP Specific IgA is an in vitro test system for the quantitative measurement of antigen specific IgA antibodies. The corresponding antigen for the specific antibody to be measured by UniCAP Specific IgA is bound to the Antigen ImmunoCAP solid phase component of the UniCAP Specific IgA system. UniCAP Specific IgA 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.

IgG

UniCAP Gliadin IgA/IgG ImmunoCAP™ is a device for the in vitro semi-quantitative measurement of IgA or IgG antibodies specific for gliadin in human serum. UniCAP Gliadin IgA/IgG 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 diagnosis of patients with celiac disease.

UniCAP Specific IgG is an in vitro test system 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 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.

(Division Sign-Off)
Division of Clinical Laboratory Devices
510(k) Number K982533

Concurrence of CDRH, Office of Device Evaluation (ODE)

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