9. 510(K) SUMMARY

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: August 15, 2005

Manufacturer/Owner:
Pharmacia Diagnostics AB
Box 6460
SE-751 37 Uppsala, Sweden
Owner/Operator Number: 9004441

Distributor/Company Contact:
Sweden Diagnostics (US) Inc.
4169 Commercial Avenue
Portage MI 49002
Registration Number: 3004973408
Martin Mann
Regulatory Affairs Manager
269-492-1957

Device Name: ImmunoCAP® Gliadin IgA

Common Name: IgA Antibodies, Gliadin

Classification:

Product Code	Class	CFR
82 MST	II	866.5750

Substantial Equivalence to: UniCAP® Gliadin IgA K982533

Note: Pharmacia Diagnostics AB is in the process of changing brand names from UniCAP to ImmunoCAP. You may notice that there are instances where we use UniCAP, ImmunoCAP/UniCAP, and ImmunoCAP in our labeling. Once we have completed the switch, the UniCAP brand name will no longer be used, to be replaced by ImmunoCAP. The ImmunoCAP brand name will be used for both our instrument systems and reagents. The original use of the ImmunoCAP brand was exclusively in conjunction with the antigen carrier.

Intended Use Statements:

ImmunoCAP/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. ImmunoCAP/UniCAP Gliadin IgA/IgG ImmunoCAP is intended to be used with the instrument ImmunoCAP/UniCAP together with reagents as stated in the Directions for Use provided with ImmunoCAP/UniCAP Specific IgA and ImmunoCAP/UniCAP Specific IgG. It is intended for in vitro diagnostic use as an aid in the diagnosis of patients with celiac disease.

ImmunoCAP/UniCAP Specific IgA is an in vitro test system for quantitative measurement of antigen specific IgA antibodies. The corresponding antigen for the specific antibody to be measured by ImmunoCAP/UniCAP Specific IgA is bound to the Antigen ImmunoCAP solid phase component of the ImmunoCAP/UniCAP Specific IgA System. ImmunoCAP/UniCAP Specific IgA assay is to be used with the instrument ImmunoCAP 100€/UniCAP 100€. 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

The Pharmacia ImmunoCAP Immunodiagnostic System is a fully integrated and automated system for immunodiagnostic testing. ImmunoCAP System is comprised currently of an instrument family, ImmunoCAP 100/250/1000 and individual assay products – Fluoro enzyme immunoassays reagents for the measurement of Immunoglobulin IgE, IgG, IgA, with ImmunoCAP Allergens/Antigens (solid phase components which contain the specific allergen/antigens to which antibodies are going to be measured), and Software Accessories.

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

ImmunoCAP instruments 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 instrument system software.

ImmunoCAP® System Information Data Manager (IDM) is intended to be used with a Windows-based PC operating up to five ImmunoCAP 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.

ImmunoCAP Specific IgA is a fluoro enzyme immunoassay for the quantitative measurement of antigen specific IgA antibodies. The corresponding antigen for the specific antibody to be measured by ImmunoCAP Specific IgA is bound to the Antigen ImmunoCAP solid phase component (ImmunoCAP carrier). 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 the ImmunoCAP carrier solid phase.
After washing away non-specific IgA, enzyme labeled antibodies against IgA (ImmunoCAP/UniCAP Specific IgA Conjugate) is added to form a complex. After incubation, unbound enzyme-anti-IgA is washed away and the bound complex is incubated with a development agent. After stopping the reaction, the response of the eluate is measured. The response is directly proportional to the concentration of IgA in the serum sample.

Device Modification Description
The modification consists of a change from polyclonal Rabbit anti-human IgA antibodies to Mouse monoclonal anti-human IgA antibodies in the reagent ImmunoCAP/UniCAP Specific IgA Conjugate. No other reagents have been changed.

Device Comparison:

Comparison results were obtained using UniCAP® Specific IgA Conjugate with polyclonal Rabbit anti-human IgA antibodies and Specific IgA Conjugate with Mouse monoclonal anti-human IgA antibodies.
Test results for a total of 182 samples (Gliadin specific IgA positive, negative and healthy individuals) covering the measuring range 1-100 mg/l were obtained and gave a good correlation between the two Conjugates.
The monoclonal Specific IgA Conjugate gave a bit lower level of response values but the small difference is considered to be fully acceptable in regard to the indication for use of the test. No change is made to the Indication for Use or clinical claims.
Other performance studies which were run covered analytical specificity and sensitivity, dilution of samples, precision and expected values of healthy individuals. All results showed very good conformance and were totally acceptable.

Conclusion

In summary, all available data support the conclusion that the modified device is substantially equivalent to the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

FEB 7 2006

Pharmacia Diagnostics AB
c/o Mr. Martin Mann
Regulatory Affairs Manager
Sweden Diagnostics (US)
4169 Commercial Avenue
Portage, MI 49002

Re: k052793
Trade/Device Name: ImmunoCAP®/UniCAP® Gliadin IgA/IgG and ImmunoCAP®/UniCAP® Specific IgA
Regulation Number: 21 CFR 866.5750
Regulation Name: Radioallergosorbent immunological test system
Regulatory Class: Class II
Product Code: MST
Dated: September 10, 2005
Received: October 3, 2005

Dear Mr. Mann:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and 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) that do not require approval of a premarket approval application (PMA). 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 (PMA), 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 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 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), please contact the Office of Compliance at (240) 276-0484. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Robert L. Becker, Jr., M.D., Ph.D.
Director
Division of Immunology and Hematology Devices
Office of In Vitro Diagnostic Device Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K 052793

Device Name: **ImmunoCAP/UniCAP® Gliadin IgA/IgG ImmunoCAP (AGf98) and ImmunoCAP/UniCAP® Specific IgA**

Indications For Use:

ImmunoCAP/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. ImmunoCAP/UniCAP Gliadin IgA/IgG ImmunoCAP is intended to be used with the instrument ImmunoCAP/UniCAP together with reagents as stated in the Directions for Use provided with ImmunoCAP/UniCAP Specific IgA and ImmunoCAP/UniCAP Specific IgG. It is intended for in vitro diagnostic use as an aid in the diagnosis of patients with celiac disease.

ImmunoCAP/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 ImmunoCAP/UniCAP Specific IgA is bound to the Antigen ImmunoCAP solid phase component of the ImmunoCAP/UniCAP Specific IgA system. ImmunoCAP/UniCAP Specific IgA assay is to be used with the instrument ImmunoCAP/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.

Prescription Use __X____ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 807 Subpart C)

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

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

Division Sign-Off

Office of In Vitro Diagnostic Device Evaluation and Safety

510(k) K052793