JUN 9 - 2005

Attachment 4

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.

Premarket Notification 510(k) Number: K051218

Date of Summary Preparation: April 25, 2005

Distributor:
Sweden Diagnostics (US) Inc.
4169 Commercial Avenue
Portage, MI 49002
269-492-1957

Manufacturer:
Pharmacia Diagnostics AB
P.O. Box 6460
SE-751 37 Uppsala, Sweden

Company Contact Person:
Martin Mann
Regulatory Affairs Manager
Sweden Diagnostics (US) Inc.
4165 Commercial Avenue
Portage, MI 49002
269-492-1957

Device Name: UniCAP Specific IgE

Common Name: Automated *in vitro* quantitative assay for the measurement of allergen specific IgE antibodies.

Classification:

Product Name	**Product Code**	**Class**	**CFR**
UniCAP Specific IgE	82DHB	II	866.5750

Substantial Equivalence to: UniCAP Specific IgE (K962274)

Indications For Use Statement:

UniCAP Specific IgE is an *in vitro* quantitative assay for the measurement of allergen specific IgE in human serum or plasma. It is intended for *in vitro* diagnostic use as an aid in the clinical diagnosis of IgE mediated allergic disorders in conjunction with other clinical findings, and is to be used in clinical laboratories, as well as physician office laboratories.

General Description:

Reagents

UniCAP Specific IgE Conjugate, ImmunoCAP Specific IgE Calibrators 0-100, UniCAP Specific IgE Curve Controls, Specific IgE Anti-IgE ImmunoCAP and Allergen ImmunoCAP Carriers. UniCAP Development Kit and UniCAP/Pharmacia CAP System Washing Solution are needed for final development of fluorescence response and washing steps between incubations.

Instrument System

ImmunoCAP instruments with built-in software, process all steps of the assay and print results automatically after the assay is completed.

UniCAP Specific IgE, Test Principle

The allergen of interest, covalently coupled to ImmunoCAP, reacts with the specific IgE in the patient sample. After washing away non-specific IgE, enzyme labeled 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. The higher the response value, the more specific IgE is present in the specimen. To evaluate the test results, the responses for the patient samples are transformed to concentrations with the use of a calibration curve.

Device Modification Description:

The modification is a minor change of the calibrator system in order to extend the technical measuring range for specific IgE antibodies below 0.35 kU_A/l. The change includes the addition of 0 kU/l Calibrator and the removal of the 50 kU/l Calibrator, keeping the same number (6) of calibrators in the kit (0, 0.35, 0.7, 3.5, 17.5 and 100 kU/l).

No changes are made to the Intended Use or in the clinical claims. Neither the assay procedure nor material has been changed in any way.

This makes it possible to measure allergen specific IgE antibodies down to the Limit of Quantitation.

Device Comparison and verification:

Comparison between the current and modified calibration curves were made to investigate the conformity between the calibration curves.

The extension of the technical measurement range from 0.35-100 kU_A/l to 0.1-100 kU_A/l, affects the technical sensitivity of the assay, the Limit of Quantitation, and therefore the verification test was performed as Limit of Quantitation (1).

Data results:

Comparison between the current and modified calibration curves gave the same results – conformity was good.

The overall Limit of quantitation (1) for allergen specific IgE antibodies was determined to be 0.1 kU_A/l.

These results show that the modified calibration curve give substantially equivalent results and also allow reporting of IgE antibody concentrations below 0.35 kU_A/l.

References:

1. Protocols for Determination of Limits of Detection and Limits of Quantitation; Approved Guideline. NCCLS document EP-17A, Volume 24, Number 34, (ISBN 1-56238-551-8) October 2004.
2. Radioallergosorbent Test (RAST) Methods for Allergen-Specific Immunoglobulin E (IgE) 510(k)s;Final Guidance for Industry and FDA

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

JUN 9 - 2005

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

Re: k051218
Trade/Device Name: UniCAP Specific IgE
Regulation Number: 21 CFR 866.5750
Regulation Name: Radioallergosorbent (RAST) Immunological Test System
Regulatory Class: Class II
Product Code: DHB
Dated: May 11, 2005
Received: May 12, 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.

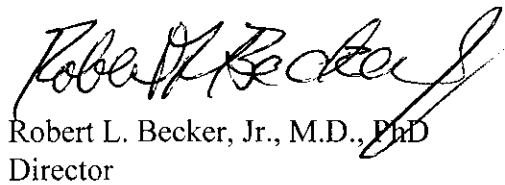
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish 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 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) 276-0131. 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/dsma/dsmamain.html

Sincerely yours,



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

Enclosure

Attachment 2

Indications for Use Statement

510(k) Number (if known) K051218

Device Name *UniCAP Specific IgE*

Indications for Use

UniCAP Specific IgE is an *in vitro* quantitative assay for the measurement of allergen specific IgE in human serum or plasma. UniCAP Specific IgE is to be used with the instrument ImmunoCAP/UniCAP 250 and ImmunoCAP/UniCAP 1000. It is intended for *in vitro* diagnostic use as an aid in the clinical diagnosis of IgE mediated allergic disorders in conjunction with other clinical findings, and is to be used in clinical laboratories.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ___X_____ OR Over-The-Counter Use_____
(Per 21 CFR 801. 109)

Maria Chan
Division Sign-Off

Office of In Vitro Diagnostic
Device Evaluation and Safety

510(k) K051218

Indications for Use Statement

510(k) Number (if known) K051218

Device Name *UniCAP Specific IgE*

Indications for Use

The UniCAP Specific IgE is an *in vitro* quantitative assay for the measurement of allergen specific IgE in human serum or plasma. UniCAP Specific IgE is to be used with the instrument ImmunoCAP 100/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 clinical 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)

Prescription Use ___X___ OR Over-The-Counter Use _____
(Per 21 CFR 801. 109)

Maria Chan

Division Sign-Off

Office of In Vitro Diagnostic Device Evaluation and Safety

510(k) K051218