8. 510(k) 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.

Assigned 510(k) Number: K072661

Date of Summary Preparation: September 20, 2007

Manufacturer:
Phadia AB
Rapsgatan 7
SE-751 37 Uppsala, Sweden

NOV 2 0 2007

510 (k) Contact Person:
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Device Name:
ImmunoCAP™ Thyroglobulin ImmunoCAP
ImmunoCAP™ Thyroid Peroxidase ImmunoCAP
ImmunoCAP™ Thyroglobulin IgG Antibodies Controls NLH
ImmunoCAP™ Thyroid Peroxidase IgG Antibodies Controls NLH

Common Name:
Thyroid Autoantibodies immunological test system

Classification

Product Name	Product Code	Class	CFR
ImmunoCAP™ Thyroglobulin	JNL	II	866.5870
ImmunoCAP™ Thyroglobulin IgG Antibodies Controls NLH	JNL	II	866.5870
ImmunoCAP™ Thyroid Peroxidase	JZO	II	866.5870
ImmunoCAP™ Thyroid Peroxidase IgG Antibodies Controls NLH	JZO	II	866.5870

Substantial Equivalence to

UniCAP TG Antibodies	510(k) number: k981559
UniCAP TPO Antibodies	510(k) number: k981930

Intended Use Statements of the Modified Devices

ImmunoCAP Thyroglobulin is a device for the *in vitro* quantitative measurement of IgG antibodies specific for Thyroglobulin (TG) in human serum and plasma. ImmunoCAP Thyroglobulin is intended to be used with the ImmunoCAP 100^{c} and ImmunoCAP 250 instruments. 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 physicians office laboratories.

ImmunoCAP Thyroid Peroxidase is a device for the in vitro quantitative measurement of IgG antibodies specific for Thyroid Peroxidase (TPO) in human serum and plasma. ImmunoCAP Thyroid Peroxidase is intended to be used with the ImmunoCAP 100C and ImmunoCAP 250 instruments. It is intended for in vitro diagnostic use as an aid in the clinical diagnosis of certain thyroid diseases, such as autoimmune thyroiditis, Graves' disease and is to be used in clinical laboratories, as well as physicians office laboratories.

ImmunoCAP Thyroglobulin IgG Antibodies Controls NLH are intended for laboratory use in monitoring the performance of *in vitro* quantitative measurement of specific IgG Thyroglobulin antibodies in human serum. ImmunoCAP Thyroglobulin IgG Antibodies Controls are intended to be used with the instrument ImmunoCAP 100^{c} and ImmunoCAP 250.

ImmunoCAP Thyroid Peroxidase IgG Antibodies Controls NLH are intended for laboratory use in monitoring the performance of *in vitro* quantitative measurement of specific IgG Thyroid Peroxidase antibodies in human serum. ImmunoCAP Thyroid Peroxidase IgG Antibodies Controls are intended to be used with the instrument ImmunoCAP 100^{c} and ImmunoCAP 250.

Special condition for use statement

The device is for prescription use only.

Special instrument requirements

ImmunoCAP 100 / ImmunoCAP 250 are fully automated immunoassay analyzers, which include software for evaluation of test results.

General Description of the Modified Devices

The modified devices belong to a fully integrated and automated system for immunodiagnostic testing. It comprises a Fluorescence-Immunoassay test system using ImmunoCAP single wells as the solid phase and is intended to be performed on the instruments ImmunoCAP 100 and ImmunoCAP 250. The conjugate for the ImmunoCAP IgG method is mouse anti-human IgG beta-galactosidase, which uses 4-Methylumbelliferyl-ßD-Galactoside as substrate. The total IgG calibration is based on a set of six WHO-standardized IgG Calibrators derived from human serum. They are used to establish an initial calibration curve, which may be used for up to 28 days on additional assays and can be stored by the instrument. Each additional assay includes calibrator (curve) controls that have to recover in defined ranges to ensure that the stored calibration curve is still valid. The Fluorescence-Immunoassay test system includes test-, method specific and general reagents that are packaged as separate units.

Test Principle of the Modified Devices

The antigen of interest, covalently coupled to ImmunoCAP, reacts with the specific IgG antibodies in the diluted patient serum specimen. After washing away non-specific IgG, enzyme labeled antibodies against IgG are added to form a complex. After incubation, unbound enzyme-anti-IgG 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 IgG is present in the specimen. To evaluate the test results, the response for the patient samples are transformed to concentrations with the use of a calibration curve.

Device Modification Description

The modified is a non-competitive solid phase EIA. The device modifications are minor and consist of brand name changes, (UniCAP to ImmunoCAP), the addition of a blocking diluent to reduce interference from cellulose IgG antibodies, and packaging configurations. The ImmunoCAP 250 instrument has also been added to the Directions for Use, as part of the ImmunoCAP family of instruments. ImmunoCAP Thyroglobulin and ImmunoCAP Thyroid Peroxidase are used as an aid in the diagnosis of thyroid diseases, such as autoimmune thyroiditis and Graves' Disease, in conjunction with other laboratory and clinical findings.

Laboratory equivalence

The comparability of the previously cleared devices and the modified devices is supported by data including

- results obtained within a comparison studies between modified and previously cleared devices
- results obtained for clinically defined sera
- results obtained for samples from apparently healthy subjects (normal population).

In summary, all available data support that the modified devices are substantially equivalent to the previously cleared devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

NOV 2 0 2007

Phadia US Inc.
c/o Mr. Martin R. Mann
Regulatory Affairs Manager
4169 Commercial Ave
Portage, MI 49002

Re: k072661
Trade/Device Name: ImmunoCAP Thyroglobulin
ImmunoCAP Thyroid Peroxidase
ImmunoCAP Thyroglobulin IgG Antibodies Controls NLH
ImmunoCAP Thyroid Peroxidase IgG Antibodies Controls NLH
Regulation Number: 21 CFR 866.5870
Regulation Name: Thyroid autoantibodies immunological system
Regulatory Class: Class II
Product Code: JNL, JZO, JJY
Dated: October 30, 2007
Received: October 31, 2007

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). 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 information about the application of labeling requirements to your device, or questions on the promotion and advertising of your device, please contact the Office of In Vitro Diagnostic Device Evaluation and Safety at (240) 276-0450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. 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 (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

for 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: K072661

Device Name: **ImmunoCAP™ Thyroglobulin ImmunoCAP**

Indications For Use:

ImmunoCAP Thyroglobulin is a device for the *in vitro* quantitative measurement of IgG antibodies specific for Thyroglobulin (TG) in human serum and plasma. ImmunoCAP Thyroglobulin is intended to be used with the ImmunoCAP 100^{e} and ImmunoCAP 250 instruments. 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's office laboratories.

Division Sign-Off

Office of In Vitro Diagnostic Device Evaluation and Safety

510(k) K072661

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

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Indications for Use

510(k) Number: K072661

Device Name: **ImmunoCAP™ Thyroid Peroxidase ImmunoCAP**

Indications For Use:

ImmunoCAP Thyroid Peroxidase is a device for the *in vitro* quantitative measurement of IgG antibodies specific for Thyroid Peroxidase (TPO) in human serum and plasma. ImmunoCAP Thyroid Peroxidase is intended to be used with the ImmunoCAP 100^{e} and ImmunoCAP 250 instruments. It is intended for *in vitro* diagnostic use as an aid in the clinical diagnosis of certain thyroid diseases, such as autoimmune thyroiditis, Graves' disease and is to be used in clinical laboratories, as well as physician's office laboratories.

Maria M Chan
Division Sign-Off

Office of In Vitro Diagnostic Device Evaluation and Safety

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Indications for Use

510(k) Number: K072661

Device Name: **ImmunoCAP™ Thyroglobulin IgG Antibodies Controls NLH**

Indications For Use:

ImmunoCAP Thyroglobulin IgG Antibodies Controls NLH are intended for laboratory use in monitoring the performance of *in vitro* quantitative measurement of specific IgG Thyroglobulin antibodies in human serum. ImmunoCAP Thyroglobulin IgG Antibodies Controls are intended to be used with the instrument ImmunoCAP 100^{e} and ImmunoCAP 250.

Maria M Chan
Division Sign-Off

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Indications for Use

510(k) Number: K072661

Device Name: **ImmunoCAP™ Thyroid Peroxidase IgG Antibodies Controls NLH**

Indications For Use:

ImmunoCAP Thyroid Peroxidase IgG Antibodies Controls NLH are intended for laboratory use in monitoring the performance of *in vitro* quantitative measurement of specific IgG Thyroid Peroxidase antibodies in human serum. ImmunoCAP Thyroid Peroxidase IgG Antibodies Controls are intended to be used with the instrument ImmunoCAP 100^{e} and ImmunoCAP 250.

Division Sign-Off

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