JUL - 6 2006

510(k) SUMMARY

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

The assigned 510(k) number is: k061382

Submitter's Name and Address

Beckman Coulter, Inc.
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Date Prepared: June 19, 2006

Device Names

Proprietary Name:	TPO Antibody and TPO Antibody Calibrators on the Access® Immunoassay Systems
Common Name:	Immunoassay for the determination of thyroperoxydase antibodies
Classification Name:	System, Test, Thyroid Autoantibody

Predicate Device

Immulite 2000 Anti-TPO Ab

Diagnostic Products Corporation

5700 West 96th Street

Los Angeles, CA 90045-5597

510(k) Number: k991096

Device Description

The Access TPO Antibody reagents, calibrators, and the Access Immunoassay Analyzers (Access, Access 2, Synchron LXi 725, UniCel DxC 600i, and UniCel DxI 800) comprise the Access Immunoassay Systems for the determination of thyroperoxydase antibody (TPOAb) levels in human serum and plasma.

Intended Use

The Access TPO Antibody assay is a paramagnetic particle, chemiluminescent immunoassay for the quantitative determination of thyroperoxydase antibody (TPOAb) levels in human serum and plasma using the Access Immunoassay Systems. The detection of TPO antibodies is an aid in the diagnosis of autoimmune thyroid disorders.

Comparison of Technological Characteristics

Attribute	Immulite 2000 Anti-TPO Ab	Access TPO Antibody
Intended Use	For the in vitro diagnostic use with the Immulite 2000 Analyzer-for the quantitative measurement of antithyroid peroxidase (TPO) antibodies in serum and EDTA plasma, as an aid the clinical diagnosis of thyroid disease.	For the quantitative determination of TPO antibody levels in human serum and plasma.
Assay Principles	Immulite 2000 Anti-TPO Ab is a solid-phase, enzyme-labeled, chemiluminescent sequential immunometric assay.	The Access TPO Antibody assay is a sequential two-step immunoenzymatic ("sandwich") assay.
Solid Support	Beads coated with highly purified human TPO.	Paramagnetic particles coated with streptavidin and coupled to biotinylated human recombinant TPO.
Detection System	Chemiluminescent substrate.	Utilizes dioxetane-based chemiluminescent substrate; Measures light production from a chemiluminescent reaction.
Calibrator	Two levels (low and high) of lyophilized TPO autoantibodies in a human serum/buffer matrix, with preservatives.	Six levels (0, ~5, ~20, ~75, ~300, and ~1000 IU/mL) of rabbit TPO antiserum in a buffered protein solution with preservatives.

Summary of Analytical Studies

Imprecision: Imprecision was tested for concentrations from approximately 0.6 to 809 IU/mL. The within run imprecision ranged from 2.6% CV to 7.9% CV. Between-run assay imprecision ranged from 1.3% CV to 4.9% CV. Total imprecision ranged from 3.1% CV to 8.7% CV.

Dilution Recovery (Linearity): Multiple dilutions of serum samples were analyzed. Mean % recovery ranged from 86.4% to 94.9%. The following statement has been added to the TPOAb directional insert: "Due to varying antigen specificity, affinity, and avidity of TPOAb in their epitope reactions, some samples may not dilute linearly."

Methods Comparison: A comparison of 119 values using the Access TPOAb assay and a commercially available immunoassay system gave the following statistical data using Deming calculations: Range of observations=5-1000, Slope=1.0207 (95% confidence interval 0.9722 to 1.0693), Intercept=-10.9123 (95 % confidence interval -24.6421 to 2.8175), Correlation coefficient (r)=0.97. The results of the study indicate that the slope and intercept are not significantly different from one and zero respectively.

Analytical Specificity: There was no significant interference from potential sample contaminants (bilirubin, hemoglobin, human serum albumin, and triglycerides).

Stability: TPOAb reagents are stable for 56 days after opening. TPOAb calibrators are stable for 120 days after opening. The calibration is stable for 56 days.

Summary of Clinical Studies

Expected Values: Sera samples were obtained in the United States from a healthy male population <30 years of age following the critiera outlined by the National Academy of Clinical Biochemists (NACB) for establishing a normal reference range for the Access TPOAb assay. A 95% non-parametric determination of results gave an upper reference limit below 9 IU/mL.

Additionally, 679 normal samples were collected in the United States from both males and females ranging in age from 18-80 years old. The screening criteria included serum TSH levels between 0.5 and 2.0 mIU/L, no goiter, no personal or family history of thyroid disease, and absence of non-thyroid autoimmune disease. After completing the screen, 492 samples were tested. 93% of these samples fell below 9 IU/mL.

Clinical Sensitivity: The Access TPO Antibody assay was evaluated using sera obtained from 54 patients diagnosed with Hashimoto's Thyroiditis and 40 patients diagnosed with Graves' Disease. 100% of the Hashimoto's Thyroiditis patients and 77.5% of the Graves' Disease samples tested positive in the Access TPO Antibody assay.

Conclusion

TPO Antibody and TPO Antibody Calibrators on the Access Immunoassay Systems is substantially equivalent to the Immulite 2000 Anti-TPO Ab for the quantitative determination of thyroperoxydase levels in human serum and plasma.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

JUL - 6 2006

Beckman Coulter, Inc.
c/o Ms. Valynda L. Machen
Senior Regulatory Specialist
1000 Lake Hazeltine Dr.
Chaska, MN 55318-1084

Re: k061382
Trade/Device Name: Access TPO Antibody Assay and Access TPO Antibody Calibrators
Regulation Number: 21 CFR 866.5870
Regulation Name: Thyroid Autoantibody Immunological Test System
Regulatory Class: Class II
Product Code: JZO, JIT
Dated: May 17, 2006
Received: May 18, 2006

Dear Ms. Machen:

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 (240) 276-3150 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): k061382

Device Name: Access TPO Antibody Assay

Indications For Use:

The Access TPO Antibody assay is a paramagnetic particle, chemiluminescent immunoassay for the quantitative determination of thyroperoxidase antibody (TPOAb) levels in human serum and plasma using the Access Immunoassay Systems.

The detection of TPO antibodies is an aid in the diagnosis of thyroid autoimmune disorders.

Prescription Use X 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 In Vitro Diagnostic Devices (OIVD)

Division Sign-Off

Office of In Vitro Diagnostic Device Evaluation and Safety

510(k) K061382