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: **k062516**

OCT - 5 2006

Applicant:	Beckman Coulter, Inc. Immunodiagnostics Development Center 1000 lake Hazeltine Drive Chaska, MN 55318
Contact Person:	Tyler Foutch Regulatory Affairs Specialist Phone: 952.368.1653 Fax: 952.368.7610
Date Prepared:	September 26, 2006
Proprietary Name:	Thyroglobulin Antibody II and Thyroglobulin Antibody II Calibrators on the Access® Immunoassay Systems
Common Name:	Immunoassay for the determination of thyroglobulin antibodies
Classification Name:	System, Test, Thyroid Autoantibody
Product Classification:	Class II
Product Code:	Reagent– DDC Calibrator Secondary- JIT
Predicate Device:	Access® Thyroglobulin Antibody Assay – K012208
Device Description:	The Access Thryoglobulin Antibody II 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 thyroglobulin antibody (TgAb) levels in human serum and plasma.
Intended Use:	The Access Thyroglobulin Antibody II (TgAb) assay is a paramagnetic particle, chemiluminescent immunoassay for the quantitative determination of thyroglobulin antibody levels in human serum and plasma using the Access Immunoassay Systems. The measurement of thyroid autoantibodies may aid in the diagnosis of Hashimoto's disease, nontoxic goiter, and Graves' disease.

Comparison of Technological Characteristics

Attribute	Access Thyroglobulin Antibody	Access Thyroglobulin Antibody II
Intended Use	For the quantitative determination of Thyroglobulin antibody levels in human serum and plasma.	For the quantitative determination of Thyroglobulin antibody levels in human serum and plasma.
Assay Principles	The Access Thyroglobulin Antibody assay is a sequential two-step immunoenzymatic ("sandwich") assay.	The Access Thyroglobulin Antibody assay is a sequential two-step immunoenzymatic ("sandwich") assay.
Solid Support	Paramagnetic particles coated with streptavidin and coupled to biotinylated human thyroglobulin.	Paramagnetic particles coated with streptavidin and coupled to biotinylated human thyroglobulin.
Detection System	Utilizes dioxetane-based chemiluminescent substrate; Measures light production from a chemiluminescent reaction.	Utilizes dioxetane-based chemiluminescent substrate; Measures light production from a chemiluminescent reaction.
Calibrator	Six levels (0, ~50, ~250, ~500, ~1000, and ~2500 IU/mL) Human thyroglobulin antibody in human serum in a buffered protein solution with preservatives.	Six levels (0, ~50, ~250, ~500, ~1000, and ~2500 IU/mL) Human thyroglobulin antibody in human serum in a buffered protein solution with preservatives.

Summary of Analytical Studies

Imprecision: Imprecision was tested for concentrations from approximately 27.0 to 721.0 IU/mL. The within run imprecision ranged from 4.0% CV to 5.8% CV. Between-run assay imprecision ranged from 2.7% CV to 5.1% CV. Total imprecision ranged from 4.8% CV to 7.0% CV. For low dose imprecision was tested for concentrations from approximately 1.7 to 10.5 IU/mL. The SD for these samples ranged from 0.3 to 0.8 SD.

Dilution Recovery (Linearity): Multiple dilutions of serum samples were analyzed. Mean % recovery ranged from 118% to 127%. Due to varying antigen specificity, affinity, and avidity of thyroglobuulin antibodies in their epitope reactions, some samples may not dilute linearly.

Methods Comparison: A comparison of 832 values using the Access Thyroglobulin Antibody II assay on the Access Immunoassay system and a commercially available enzyme immunoassay kit gave the following results using relative sensitivity, specificity and percent agreement:

	Commercially Available TgAb Assay				
		+	-	Total	
Access TgAb II Assay	+	136	3	139	Positive % Agreement = 95%
	-	7	686	693	Negative % Agreement = 99.6%
	Total	143	689	832	Percent Agreement = 99%

Analytical Sensitivity: The lowest detectable level of TgAb distinguishable from zero (Access Thyroglobulin Antibody Calibrator S0) with 95% confidence is 0.9 IU/mL. This value is determined by processing a complete six point calibration curve, controls and 20 replicates of the zero calibrator in multiple assays. The analytical sensitivity value is calculated from the curve at the point that is two standard deviations from the mean measured zero calibrator signal.

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

Summary of Clinical Studies

Expected Values: Sera samples were obtained in the United States from males < 30 years of age following the criteria outlined by the National Academy of Clinical Biochemists (NACB) for establishing a normal reference range for thyroid antibody tests. The screening criteria included serum TSH levels between 0.5 and 2.0 mIU/L, no personal or family history of thyroid disease and absence of non-thyroid autoimmune disease. 137 screened samples were tested generating a 95% non-parametric upper reference limit below 4 IU/mL.

Additionally, 519 normal samples were collected in the United States from both males and females ranging in age from 18–74 years old. The screening criteria included serum TSH levels between 0.5 and 2.0 mIU/L no personal or family history of thyroid disease, and absence of non-thyroid autoimmune disease. 519 samples were tested. 96% of these samples fell below 4 IU/mL.

Conclusion: The Access® Thyroglobulin Antibody II and Thyroglobulin Antibody II Calibrators on the Access® Immunoassay Systems is substantially equivalent to the Access Thyroglobulin Antibody for the quantitative determination of thyroglobulin antibody in human serum and plasma.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
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c/o Mr. Tyler Foutch
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1000 Lake Hazeltine Dr.
Chaska, MN 55318-1084

OCT - 5 2006

Re: k062516
Trade/Device Name: Access Thyroglobulin Antibody II 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: JNL, JIT
Dated: August 25, 2006
Received: August 28, 2006

Dear Mr. Foutch:

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): k062516

Device Name: Access Thyroglobulin Antibody II Assay

Indications for Use:

The Access Thyroglobulin Antibody II Assay provides in vitro quantitative determination of thyroglobulin antibody levels in human serum and plasma using the Access Immunoassay Systems. The measurement of thyroid autoantibodies may aid in the diagnosis of Hashimoto's disease, nontoxic goiter, and Graves' disease.

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 OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Maria Chan

Division Sign-Off

Office of In Vitro Diagnostic Device Evaluation and Safety

510(k) K062516