September 26, 2023

Beckman Coulter, Inc.
Adam Viitala
Senior Manager, Regulatory Affairs
1000 Lake Hazeltine Drive
Chaska, Minnesota 55318

Re: K213517
Trade/Device Name: Access Thyroglobulin Antibody II
Regulation Number: 21 CFR 866.5870
Regulation Name: Thyroid Autoantibody Immunological Test System
Regulatory Class: Class II
Product Code: JZO
Dated: March 10, 2023
Received: March 10, 2023

Dear Adam Viitala:

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. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. 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. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to 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 and Part 809); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Ying Mao -S

Ying Mao, Ph.D.
Branch Chief
Division of Immunology and Hematology Devices
OHT7: Office of In Vitro Diagnostics
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K213517

Device Name
Access Thyroglobulin Antibody II

Indications for Use *(Describe)*

The Access Thyroglobulin Antibody II 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.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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Immunodiagnostic Development Center
1000 Lake Hazeltine Drive
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510(k) Summary

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of 21 CFR 807.92(a)(1).

The assigned 510(k) number is K213517.

Submitted By:

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Date Prepared:

September 22, 2023

Device Name:

Proprietary / Trade Name: Access Thyroglobulin Antibody II
Common Name: Thyroid autoantibody immunological test system
Classification Description: Thyroid autoantibody immunological test system.
Classification Regulation: 21 CFR 866.5870
Classification Product Code: JZO

Predicate Device:

The modified Access Thyroglobulin Antibody II Assay claims substantial equivalence to previously cleared Access Thyroglobulin Antibody II Assay, FDA 510(k) Number K112933, cleared December 27, 2011.

Device Description:

The Access Thyroglobulin Antibody II 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.

The Access Thyroglobulin Antibody II assay consists of the reagent pack and calibrators. Other items needed to run the assay include substrate and wash buffers. The assay is run on Access 2 Immunoassay Analyzers.

The device modifications described in this submission impact the Access Thyroglobulin Antibody II reagent pack only; they do not impact or change the other components that are used with this reagent pack. The modification does not affect the intended use or indications of the device or alter the fundamental scientific technology of the device.

A description of the reagent pack is provided below.

Well	Ingredients
R1a:	Dynabeads* paramagnetic particles coated with streptavidin and coupled to biotinylated human thyroglobulin, suspended in a TRIS buffer with protein (bovine), < 0.1% sodium azide, and 0.1% ProClin** 300.
R1b:	Human thyroglobulin-alkaline phosphatase (bovine) conjugate in a TRIS buffer with protein (bovine), < 0.1% sodium azide, and 0.1% ProClin 300.
R1c:	TRIS buffer with protein (bovine), < 0.1% sodium azide and 0.1% ProClin 300.
R1d:	TRIS buffer with blocking polymer, < 0.1% sodium azide and 0.1% ProClin 300.

*Dynabead® is a registered trademark of Dynal A.S., Oslo, Norway

**ProClin™ is a trademark of The Dow Chemical Company (“Dow”) or an affiliate company of Dow.

Intended Use:

The Access Thyroglobulin Antibody II 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 to the Predicate:

The modified device and previously cleared predicate device are compared below.

Characteristic	Predicate Device Access Thyroglobulin Antibody II (k112933)	Modified Device Access Thyroglobulin Antibody II
Intended Use	The Access Thyroglobulin Antibody II 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.	Same
Analyte Measured	Thyroglobulin Antibody	Same
Technology	Sandwich immunoassay	Same
Format	Chemiluminescent	Same
Method	Automated	Same
Sample Type	Human serum or plasma	Same
Assay Throughput	Approximately 48 Minutes	Same
Sample Volume	10 uL	Same
Measuring Range	0.9-2,500 IU/mL	1.5-2,500 IU/mL
Blocker reagents	Free biotin and alkaline phosphatase not included in reagent pack	Biotin and alkaline phosphatase included in reagent pack as blockers
Biotin Interference	Specimens with biotin concentrations ≤ 100 ng/mL demonstrated non-significant bias (≤ 10%) in results. Biotin concentrations > 100 ng/mL can lead to significant (> 10%) negative bias in Thyroglobulin Ab II results.	No significant interference (± 10%) observed in samples containing up to 3,510 ng/mL of biotin.
Imprecision	SD < 1.5 for values < 15 IU/mL CV < 10% for values ≥ 15 IU/mL	SD ≤ 1.5 for values < 15 IU/mL CV ≤ 10.0% for values ≥ 15 IU/mL and < 1000 IU/mL CV ≤ 15.0% for values ≥ 1000 IU/mL

Summary of Studies:

Method Comparison: A comparison of values using the Access Thyroglobulin Antibody II assay on the Access Immunoassay system and a commercially available immunoassay gave the statistical data provided in the following table. The data was analyzed by Passing-Bablok regression and Pearon's correlation and followed the CLSI EP09c guideline.

n	Concentration Range (IU/mL)	Slope (95% CI)	Y-Intercept (95% CI)	Correlation Coefficient R
123	1.79-2216.25	1.03 (1.00-1.06)	-0.13 (-0.68-0.30)	0.99

Imprecision: The Access Thyroglobulin Antibody II assay exhibits within laboratory (total) imprecision of standard deviation (SD) ≤ 1.5 at concentrations <15 IU/mL, CV ≤10.0 % at concentrations ≥ 15 IU/mL and < 1000 IU/mL, and CV ≤ 15.0% for concentrations ≥ 1000 IU/mL.

Reproducibility: The Access Thyroglobulin Antibody II assay exhibits reproducibility of standard deviation (SD) ≤ 2.3 at concentrations <15 IU/mL, CV ≤15.0 % at concentrations ≥ 15 IU/mL and < 1000 IU/mL, and CV ≤ 20.0% for concentrations ≥ 1000 IU/mL.

High-dose Hook Effect: The Access Thyroglobulin Antibody II assay demonstrated no high-dose hook effect at concentrations up to at least 50,000 IU/mL.

Linearity: The Access Thyroglobulin Antibody II assay has been demonstrated to be linear across the range of the assay (1.5 to 2,500 IU/mL) in both serum and plasma samples.

Sensitivity: Limit of Blank (LoB), Limit of Detection (LoD), and Limit of Quantitation (LoQ) studies were conducted on multiple Access Immunoassay Systems following CLSI guideline EP17-A2. The LoB study included 2 reagent lots and 2 instruments over a minimum of 3 days. The LoD and LoQ studies included 2 reagent lots and 2 instruments over a minimum of 5 days.

	IU/mL
Limit of Blank (LoB)	0.0
Limit of Detection (LoD)	0.4
Limit of Quantitation (LoQ) ≤ 20% within-lab CV	1.5

Analytical Specificity: Samples with potential cross-reactive disease states were tested on both the modified Access Thyroglobulin Antibody II assay and the predicate

currently marketed Access Thyroglobulin Antibody II assay, and showed 100% total agreement.

Potential interferents were tested at one concentration and compared to control samples without potential interferents. Testing was completed on patient serum samples containing two levels of thyroglobulin antibody at clinically relevant concentrations of approximately 4 IU/mL and 100 IU/mL. Testing of all potential interferents, including biotin at a concentration of 3510 ng/mL, with Access TgAb found that there is no significant interference, as defined by a change in concentration between the control and the test samples within ± 1.5 IU/mL for samples below 15 IU/mL and within ± 10% for samples greater than or equal to 15 IU/mL.

Matrix Comparison: A comparison of fifty (50) matched sets of serum, lithium heparin plasma and EDTA plasma samples with thyroglobulin antibody concentrations with a range of approximately 0 IU/mL to 2,500 IU/mL were compared using Passing-Bablok linear regression analysis. The results met the acceptance criteria of slope of 1.00 ± 0.12 and $R2 \geq 0.92$.

Conclusion:
The modified device has the same intended use and fundamental scientific technology as the predicate device. The modified device is as safe and effective as the predicate device, as demonstrated through verification testing.

The information provided in this submission demonstrates that the modified device is substantially equivalent to the predicate device.