



July 3, 2024

Beckman Coulter Inc
Kate Oelberg
Senior Staff Quality and Regulatory Affairs
1000 Lake Hazeltine Drive
Chaska, Minnesota 55318

Re: K240996

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: JNL
Dated: April 11, 2024
Received: April 11, 2024

Dear Kate Oelberg:

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (<https://www.fda.gov/media/99812/download>) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (<https://www.fda.gov/media/99785/download>).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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

Indications for Use

510(k) Number (if known)
K240996

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.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRASStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

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.

510(k) Number: K240996

Date Prepared: July 2, 2024

Submitted By:

Beckman Coulter, Inc.
1000 Lake Hazeltine Drive
Chaska, MN 55318

Primary Contact:

Kate Oelberg
Senior Staff Quality and Regulatory Affairs
Phone: (612) 431-7315
Email: kmoelberg@beckman.com

Alternate Contact:

Kuljeet Kaur
Senior Manager, Regulatory Affairs
Phone: (952) 368-7816
Email: kkaur@beckman.com

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: JNL

Predicate Device

Device Name: Access Thyroglobulin Antibody II

510(k) Numbers: K213517

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 is a sequential two-step immunoenzymatic ("sandwich") assay. A sample is added to a reaction vessel with paramagnetic particles coated with the thyroglobulin protein. The TgAb in the sample binds to the thyroglobulin coated on the

particles. After incubation, materials bound to the solid phase are held in a magnetic field while unbound materials are washed away. The thyroglobulin-alkaline phosphatase conjugate is added and binds to the TgAb.

After second incubation, materials bound to the solid phase are held in a magnetic field while unbound materials are washed away. Then, the chemiluminescent substrate is added to the vessel and light generated by the reaction is measured with a luminometer. The light production is directly proportional to the concentration of analyte in the sample. Analyte concentration is automatically determined from a stored calibration.

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 to the Predicate

Characteristic	Predicate Device Access Thyroglobulin Antibody II (k213517)	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
Sample Volume	10 uL	Same
Measuring Range	1.5 -2,500 IU/mL	Same
Blocker reagents	Biotin and alkaline phosphatase included in reagent pack as blockers	Same

Biotin Interference	No significant interference ($\pm 10\%$) observed in samples containing up to 3,510 ng/mL of biotin.	Same
Imprecision	SD ≤ 1.5 for values < 15 IU/mL CV $\leq 10.0\%$ for values ≥ 15 IU/mL and < 1000 IU/mL CV $\leq 15.0\%$ for values ≥ 1000 IU/mL	Same
Instrument	Access Immunoassay system	Dxl 9000 Access Immunoassay Analyzer
Substrate	Access Substrate	Lumi-Phos Pro Substrate

Standard/Guidance Document Referenced (if applicable):

CLSI EP05-A3: Evaluation of Precision Performance of Quantitative Measurement Methods; Approved Guideline – Third Edition
 CLSI EP06-2nd Edition-: Evaluation of the Linearity of Quantitative Measurement Procedures: A Statistical Approach; Approved Guideline
 CLSI EP17-A2: Evaluation of Detection Capability for Clinical Laboratory Measurement Procedures; Approved Guideline – Second Edition
 CLSI EP09c 3rd Edition: Measurement Procedure Comparison and Bias Estimation Using Patient Samples; Third Edition

Summary of Studies

Method Comparison: A study based on CLSI EP09c, 3rd Edition using Passing-Bablok regression and Pearson’s correlation compared the Access 2 Immunoassay System and the Dxl 9000 Access Immunoassay Analyzer.

N	Concentration Range* (IU/mL)	Slope	Slope 95% CI	Intercept	Intercept 95% CI	Correlation Coefficient R
114	2.3 – 2,463	0.97	0.95 – 0.99	-0.37	-0.99 – 0.047	1.00

*Range is Access 2 values

Imprecision: The assay was designed to have within-laboratory imprecision as listed below:

- ≤ 1.5 IU/mL SD at concentrations < 15 IU/mL
- $\leq 10.0\%$ CV at concentrations ≥ 15 IU/mL and $< 1,000$ IU/mL
- $\leq 15.0\%$ CV at concentrations $\geq 1,000$ IU/mL

A study based on CLSI EP05-A312 performed on the Dxl 9000 Access Immunoassay Analyzer tested multiple samples in duplicate in 2 runs per day for a minimum of 20 days.

Concentration (IU/mL)			Repeatability (Within-run)		Between-run		Between-day		Within-Laboratory	
Sample	N	Mean	SD	%CV	SD	%CV	SD	%CV	SD	%CV
Sample 1	80	2.4	0.1	4.2	0.1	2.5	0.1	2.0	0.1	5.2
Sample 2	80	188	6.6	3.5	0.0	0.0	3.9	2.1	7.6	4.1
Sample 3	80	727	22.0	3.0	0.0	0.0	21.3	2.9	30.6	4.2

Sample 4	80	1493	35.5	2.4	39.9	2.7	51.2	3.4	74.0	5.0
Sample 5	80	1925	53.5	2.8	56.9	3.0	80.9	4.2	112.5	5.8

Reproducibility: A study based on CLSI EP05-A312 performed on the Dxl 9000 Access Immunoassay Analyzer tested multiple samples in replicates of 5 per day for a minimum of 5 days on 3 instruments.

Concentration (IU/mL)			Repeatability (Within-run)		Between-day		Between - instrument		Reproducibility	
Sample	N	Mean	SD IU/mL	%CV	SD IU/mL	%CV	SD IU/mL	%CV	SD IU/mL	%CV
Sample 1	75	2.6	0.1	4.7	0.1	1.9	0.1	2.8	0.2	5.8
Sample 2	75	184	4.1	2.2	2.9	1.6	4.8	2.6	6.9	3.8
Sample 3	75	744	19.2	2.6	12.1	1.6	2.5	0.3	22.8	3.1
Sample 4	75	1503	43.9	2.9	15.2	1.0	26.3	1.8	53.4	3.6
Sample 5	75	1966	68.2	3.5	102.2	5.2	23.9	1.2	125.1	6.4

Linearity: A study based on CLSI EP06-Ed2 performed on the Dxl 9000 Access Immunoassay Analyzer determined the assay demonstrated linearity across the measuring interval.

Detection Capability:

Limit of Blank (LoB), Limit of Detection (LoD), and Limit of Quantitation (LoQ) studies were conducted on the Dxl 9000 Access Immunoassay Analyzer following CLSI EP17-A2.

	IU/mL
Limit of Blank (LoB)	0.1
Limit of Detection (LoD)	0.2
Limit of Quantitation (LoQ) ≤ 20% within-lab CV	1.5

Substantial Equivalence Comparison Conclusion

Beckman Coulter’s Access Thyroglobulin Antibody II assay on the Dxl 9000 Access Immunoassay Analyzer is substantially equivalent to the Access Thyroglobulin Antibody II assay on the Access 2 Immunoassay System as demonstrated through the information and data provided in this submission. The performance testing presented in this submission provides evidence that the device is safe and effective in its intended use.