June 28, 2024

Beckman Coulter, Inc.
Muhammad Sheikh
Staff Regulatory Affairs
Beckman Coulter Inc
1000 Lake Hazeltine Drive
Chaska, Minnesota 55318

Re: K240927
Trade/Device Name: Access Thyroglobulin
Regulation Number: 21 CFR 866.6010
Regulation Name: Tumor-Associated Antigen Immunological Test System
Regulatory Class: Class II
Product Code: MSW
Dated: April 4, 2024
Received: April 4, 2024

Dear Muhammad Sheikh:

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

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 07/31/2026
See PRA Statement below.

510(k) Number *(if known)*
K240927

Device Name
Access Thyroglobulin

Indications for Use *(Describe)*
Access Thyroglobulin assay is a paramagnetic particle, chemiluminescent immunoassay for the quantitative determination of thyroglobulin levels in human serum and plasma using the Access Immunoassay Systems. This device is intended to aid in monitoring for the presence of persistent or recurrent/metastatic disease in patients who have differentiated thyroid cancer (DTC) and have had thyroid surgery (with or without ablative therapy), and who lack serum thyroglobulin antibodies.

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.

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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 SMDA 1990 and 21 CFR 807.92.

510(k) assigned number: K240927

Submitter Name and Address:

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Date Prepared:

June 20, 2024

Device Name:

Proprietary / Trade Name: Access Thyroglobulin
Common Name: Thyroglobulin Chemiluminescence Immunoassay Classification
Description: Tumor-associated antigen immunological test system
Classification Regulation: 21 CFR 866.6010
Classification Product Code: MSW

Predicate Device:
The modified Access Thyroglobulin assay claims substantial equivalence to previously cleared Access Thyroglobulin assay, FDA 510(k) Number K220972, cleared September 15, 2023.

Device Description:

The Access Thyroglobulin assay consists of the reagent pack and calibrators. Other items needed to run the assay include the Access Thyroglobulin Sample Diluent, substrate and wash buffer. The Access Tg assay along with the Access wash buffer and substrate are designed for use with the Access Immunoassay Systems in a clinical laboratory setting.

Lumi-Phos PRO substrate was used with this pack. The modification does not affect the 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 mouse monoclonal antithyroglobulin antibodies, suspended in a TRIS buffer with protein (bovine), < 0.1% sodium azide, and 0.1% ProClin** 300.
R1b:	Mouse monoclonal anti-thyroglobulin-alkaline phosphatase (bovine) conjugate in a TRIS buffer with protein (bovine, murine), < 0.1% sodium azide, and 0.1% ProClin 300.
R1c:	HEPES buffer with protein (bovine and mouse), < 0.1% sodium azide, and 0.5% 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:
Access Thyroglobulin assay is a paramagnetic particle, chemiluminescent immunoassay for the quantitative determination of thyroglobulin levels in human serum and plasma using the Access Immunoassay Systems. This device is intended to aid in monitoring for the presence of persistent or recurrent/metastatic disease in patients who have differentiated thyroid cancer (DTC) and have had thyroid surgery (with or without ablative therapy), and who lack serum thyroglobulin antibodies.

Comparison to the Predicate:

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

Characteristic	Predicate Device Access Thyroglobulin (K241423)	Modified Device Access Thyroglobulin
Intended Use	Access Thyroglobulin assay is a paramagnetic particle, chemiluminescent immunoassay for the quantitative determination of thyroglobulin levels in human serum and plasma using the Access Immunoassay Systems. This device is intended to aid in monitoring for the presence of persistent or recurrent/metastatic disease in patients who have differentiated thyroid cancer (DTC) and have had thyroid surgery (with or without ablative therapy), and who lack serum thyroglobulin antibodies.	Same
Analyte Measured	Thyroglobulin	Same
Technology	Sandwich immunoassay	Same
Format	Chemiluminescent	Same
Method	Automated	Same
Assay architecture	Biotinylated mouse monoclonal antithyroglobulin antibodies pre-coupled to paramagnetic particles coated with streptavidin	Same
Antibodies	Mouse monoclonal antibodies	Same
Biotin Interference	No significant interference (± 10%) observed in samples containing up to 3,510 ng/mL of biotin.	Same
Measuring Range	0.1 - 500 ng/mL	Same
Sample Type	Human serum or plasma	same
Sample Volume	40 µL	45 µL
Substrate	Access Substrate	Lumi-Phos PRO substrate
Instrument	Access 2 Immunoassay Analyzer	DxI 9000 Access Immunoassay Analyzer

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: Measurement Procedure Comparison and Bias Estimation Using Patient Samples– Third Edition

Summary of Studies:

Method Comparison: A comparison of values using the Access Thyroglobulin assay on DxI 9000 Immunoassay Analyzer and Access 2 Immunoassay System gave the statistical data provided in the following table. The data was analyzed by Passing-Bablok regression and Pearson's correlation and followed the CLSI EP09c guideline.
*Values are from predicate device.

DxI 9000 Instrument #	N	Concentration Range* (ng/mL)	Slope (95% CI)	Intercept (95% CI)	Correlation Coefficient R
All Combined	187	0.35 – 4.73	1.00 (0.99 – 1.00)	0.0044 (-0.029 – 0.021)	1.00

*Range is Access 2 values.

Imprecision: The Access Thyroglobulin assay exhibits within laboratory (total) imprecision of CV ≤ 10.0% at concentrations > 1.0 ng/mL and standard deviation (SD) ≤ 0.1 ng/mL at concentrations ≤ 1.0 ng/mL.

A study based on CLSI EP05-A3 performed on a DxI 9000 Immunoassay Analyzer tested multiple samples in duplicate in 2 runs per day for 20 days. The representative imprecision data is provided in the following table.

Concentration (ng/mL)			Repeatability (Within-run)		Between-run		Between-day		Within-Laboratory (Total)	
Sample	N	Mean	SD	%CV	SD	%CV	SD	%CV	SD	%CV
Sample 1	88	0.30	0.02	5.4	0.01	4.7	0.01	4.4	0.02	8.4
Sample 2	88	5.5	0.26	4.7	0.26	4.7	0.09	1.6	0.38	6.8
Sample 3	88	22	0.95	4.4	0.88	4.1	0.41	1.9	1.36	6.3
Sample 4	80	111	2.22	2.0	0.64	0.6	1.47	1.3	2.74	2.5
Sample 5	80	376	8.91	2.4	5.04	1.3	9.06	2.4	13.67	3.6
Sample 6	80	417	8.82	2.1	6.25	1.5	10.13	2.4	14.82	3.6

Reproducibility: A reproducibility study based on CLSI EP05-A316 performed on the DxI 9000 Access Immunoassay Analyzer tested multiple samples in replicates of 5 per day for a minimum of 5 days on 3 instruments.

Concentration (ng/mL)			Repeatability (Within-run)		Between-day		Between - instrument		Reproducibility	
Sample	**N**	**Mean**	**SD**	**%CV**	**SD**	**%CV**	**SD**	**%CV**	**SD**	**%CV**
Sample 1	75	0.34	0.02	5.9	0.02	4.5	0.00	0.0	0.03	7.4
Sample 2	75	6.2	0.20	3.2	0.09	1.5	0.18	2.9	0.28	4.6
Sample 3	75	21	0.82	3.9	0.49	2.3	0.69	3.3	1.18	5.7
Sample 4	75	109	2.98	2.7	1.62	1.5	0.92	0.8	3.51	3.2
Sample 5	75	370	11.84	3.2	6.37	1.7	13.31	3.6	18.92	5.1
Sample 6	75	402	10.18	2.5	13.09	3.3	16.94	4.2	23.70	5.9

Linearity: A study based on CLSI EP06-Ed215 performed on the DxI 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 DxI 9000 Access Immunoassay Analyzer following CLSI guideline EP17-A2. The LoB study included multiple reagent lots and 2 instruments over a minimum of 3 days. The LoD and LoQ studies included multiple reagent lots and a minimum of 5 days.

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	DxI 9000 Immunoassay Analyzer
	ng/mL
Limit of Blank (LoB)	0.03
Limit of Detection (LoD)	0.05
Limit of Quantitation (LoQ) ≤20% within-lab CV	0.1

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.