September 15, 2023

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

Re: K220972
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: January 26, 2023
Received: January 26, 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)*
K220972

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 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.

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Immunodiagnostic Development Center
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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 K220972

Submitted By:

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Date Prepared:

September 14, 2023

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 K002905, cleared October 19, 2000.

Device Description:

Access Thyroglobulin assay is a paramagnetic particle, chemiluminescent immunoassay for the quantitative determination of thyroglobulin levels in human serum 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.

The Access Tg assay consists of the reagent pack and calibrators. Other items needed to run the assay include the Access Tg 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.

The device modification described in this submission impacts the Access Thyroglobulin reagent pack only; the change does 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 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 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 (k002905)**	**Modified Device Access Thyroglobulin**
Intended Use	The Access Thyroglobulin (Tg) 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 local and metastatic thyroid tissue in patients who have had thyroid gland ablation (using thyroid surgery with or without radioactivity) and who lack serum thyroglobulin antibodies.	Access Thyroglobulin assay is a paramagnetic particle, chemiluminescent immunoassay for the quantitative determination of thyroglobulin levels in human serum 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.
Analyte Measured	Thyroglobulin	Same
Technology	Sandwich immunoassay	Same
Format	Chemiluminescent	Same
Method	Automated	Same
Sample Type	Human serum or plasma	Human serum
Assay Throughput	Approximately 42 Minutes	Same
Sample Volume	40 μL	Same

Measuring Range	0.1 - 500 ng/mL	Same
Assay architecture	Biotinylated mouse monoclonal antithyroglobulin antibodies not pre-coupled to paramagnetic particles coated with streptavidin	Biotinylated mouse monoclonal antithyroglobulin antibodies pre-coupled to paramagnetic particles coated with streptavidin
Antibodies	Mouse monoclonal antibodies	Same
Biotin Interference	Specimens with biotin concentrations ≤ 10 ng/mL demonstrated non-significant bias (≤ 10%) in results. Biotin concentrations > 10 ng/mL can lead to significant (> 10%) negative bias in Thyroglobulin results.	No significant interference (≤± 10%) observed in samples containing up to 3,510 ng/mL of biotin.

Summary of Studies:

Method Comparison: A comparison of 102 serum samples with thyroglobulin concentrations within the assay's measuring range were run on both the modified Access Thyroglobulin assay and the predicate currently marketed Access Thyroglobulin assay. The results were compared using Passing-Bablok regression and Pearson's correlation with the predicate on the x-axis. The results of the method comparison study met the acceptance criteria of R ≥ 0.90 and slope 1.00 ± 0.09.

Imprecision: A study based on CLSI EP05-A3 performed on an Access Immunoassay System tested multiple samples in duplicate in 2 runs per day for 20 days. The representative imprecision data is provided in the following table.

Sample	N	Mean (ng/mL)	Within-Run		Between-Run		Between-Day		Total	
			SD	%CV	SD	%CV	SD	%CV	SD	%CV
1	80	0.11	0.01	8.4	0.01	4.7	0.00	0.0	0.01	9.6
2	80	0.17	0.01	6.2	0.02	14.0	0.01	4.3	0.03	15.9
3	80	4.5	0.09	2.1	0.06	1.3	0.05	1.0	0.12	2.6
4	80	21	0.4	1.9	0.0	0.0	0.2	0.9	0.5	2.2
5	80	133	2.2	1.6	1.7	1.2	0.0	0.0	2.7	2.1
6	80	431	7.2	1.7	8.5	2.0	18.4	4.3	21.5	5.0

Reproducibility: Two reproducibility studies based on CLSI EP05-A3 performed on the Access Immunoassay System tested multiple samples in replicates of 3 or 5 over a 5 day period of time. Study 1 consisted of 3 replicates of 2 samples tested with 2 runs per day for 5 days on 3 instruments. Study 2 consisted of 5

replicates of 3 samples with 3 runs per day over 5 days one 1 instrument. The representative reproducibility data is provided in the following table.

Study	Mean (ng/mL)	N	Repeatability (within-run)		Between-day		Between-instrument		Reproducibility	
			SD (ng/mL)	% CV	SD (ng/mL)	% CV	SD (ng/mL)	% CV	SD (ng/mL)	% CV
1	4.3	90	0.07	1.7	0.04	1.0	0.10	2.3	0.15	3.6
	20	90	0.27	1.3	0.00	0.0	0.57	2.8	0.74	3.6
2	0.48	75	0.01	2.9	0.01	2.2	0.01	2.0	0.02	4.2
	136	75	2.44	1.8	1.43	1.1	3.01	2.2	4.13	3.0
	446	75	10.74	2.4	8.15	1.8	0.00	0.0	13.48	3.0

High-dose Hook Effect: The Access Thyroglobulin assay demonstrated no high-dose hook effect at concentrations up to at least 40,000 ng/mL.

Linearity: The Access Thyroglobulin assay has been demonstrated to be linear across the range of the assay (0.1 to approximately 500 ng/mL) in serum samples.

Dilution Recovery: The Access Thyroglobulin assay has been demonstrated to dilute recover across and above the range of the assay in serum samples.

Limit of Blank (LoB): The Access Thyroglobulin assay was designed to have a Limit of Blank of ≤ 0.03 ng/mL. In one study, LoB testing determined the LoB for Access Thyroglobulin to be 0.02 ng/mL.

Limit of Detection (LoD): The Access Thyroglobulin assay was designed to have a Limit of Detection (LOD) of ≤ 0.05 ng/mL in serum samples. In one study, LoD testing determined the LoD for Access Thyroglobulin to be 0.05 ng/mL.

Limit of Quantitation (LoQ): The Access Thyroglobulin assay was designed to have a Limit of Quantitation (LOD) of ≤ 0.1 ng/mL in serum samples. In one study, the LoQ for Access Thyroglobulin was determined to be 0.05 ng/mL.

Analytical Specificity: Potential cross-reactive substances were added to serum patient samples at two concentrations of thyroglobulin (approximately 20 ng/mL and 100 ng/mL). Stock solutions of potential cross-reactants were prepared and added directly to the serum in no more than 5% (v/v) final concentration. Control samples were prepared in the same manner without the cross-reactant added. Testing of 3,3',5-Triiodo-L-thyronine (T3), L-Thyroxine (T4), Thyroxine Binding Globulin (TBG) and Thyroid Stimulating Hormone (TSH) with Access Thyroglobulin found that there is no significant cross-reactivity, as defined by a change in concentration between the diluent control and the test samples within ± 10%.

Potential interferents were tested at one concentration and compared to control samples without potential interferents. The results were reported as a percent difference between test and control sample. Testing was completed on patient serum samples containing two levels of Thyroglobulin at clinically relevant concentrations of approximately 25.0 ng/mL and 100.0 ng/mL. Testing of all potential interferents, including biotin at a concentration of 3510 ng/mL, with Access Thyroglobulin found that there is no significant interference, as defined by a change in concentration between the diluent control and the test samples within $\leq \pm$ 10%.

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.