May 10, 2024

Beckman Coulter, Inc
Kuljeet Kaur
Senior Manager Regulatory Affairs
1000 Lake Hazeltine Drive
Chaska, Minnesota 55318

Re: K240479
Trade/Device Name: Access OV Monitor
Regulation Number: 21 CFR 866.6010
Regulation Name: Tumor-Associated Antigen Immunological Test System
Regulatory Class: Class II
Product Code: LTK
Dated: February 19, 2024
Received: February 20, 2024

Dear Kuljeet Kaur:

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.

Submission Number *(if known)*

K240479

Device Name

Access OV Monitor

Indications for Use *(Describe)*

The Access OV Monitor assay is a paramagnetic particle, chemiluminescent immunoassay for the quantitative determination of CA 125 antigen levels in human serum and plasma using the Access Immunoassay Systems. This device is indicated for use in the measurement of CA 125 antigen to aid in the management of ovarian cancer patients. Serial testing for patient CA 125 antigen concentrations should be used in conjunction with other clinical methods used for monitoring ovarian cancer.

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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510(k) Summary

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21CFR807.92.

510(k) Number: K240479 Date Prepared: May 01, 2024

Submitter Name and Address:
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Trade Name: Access OV Monitor
Common Name: OV Monitor Chemiluminescence Immunoassay
Classification Regulation: 21 CFR 866.6010
Classification Product Code: LTK

Predicate Device:
Access OV Monitor
510(k) Number K023597

Device Description

The Access OV Monitor assay is a sandwich immunoenzymatic assay. The Access OV Monitor assay consists of the reagent pack and calibrators. Other items needed to run the assay include substrate and wash buffer. The Access OV Monitor assay reagent pack, Access OV Monitor assay calibrators, along with the UniCel DxI Wash Buffer II are designed for use with the DxI 9000 Access Immunoassay Analyzer in a clinical laboratory setting.

Intended Use

The Access OV Monitor assay is a paramagnetic particle, chemiluminescent immunoassay for the quantitative determination of CA 125 antigen levels in human serum and plasma using the Access Immunoassay Systems. This device is indicated for use in the measurement of CA 125 antigen to aid in the management of ovarian cancer patients. Serial testing for patient CA

125 antigen concentrations should be used in conjunction with other clinical methods used for monitoring ovarian cancer.

Comparison of Technological Characteristics to the Predicate (Assay)

System Attribute/Characteristic	Predicate Access OV Monitor assay (k023597) run on the Access Immunoassay System	Access OV Monitor assay run on the DxI 9000 Access Immunoassay Analyzer Instrument
Intended Use/ Indications for Use	The Access OV Monitor assay is a paramagnetic particle, chemiluminescent immunoassay for the quantitative determination of CA 125 antigen levels in human serum and plasma using the Access Immunoassay Systems. This device is indicated for use in the measurement of CA 125 antigen to aid in the management of ovarian cancer patients. Serial testing for patient CA 125 antigen concentrations should be used in conjunction with other clinical methods used for monitoring ovarian cancer.	Same
Analyte Measured	CA 125	Same
Standardization	Working Calibrators	Same
Technology	chemiluminescent	Same
Format	Sandwich Immunoassay	Same
Method	Automated	Same
Calibration	Utilizes a stored calibration curve	Same
Sample Type	Serum/Plasma	Same
Stability	28 days after opening	Same
Reagent Pack formulation and packaging	Access Reagent Pack formulation and packaging.	Same
Reagent Configurations	One Configuration: 100 determinations, 2 packs, 50 tests/pack	Same
Measuring Range	0.5 – 5000 U/mL	2.0 – 5,000 U/mL
Sample Volume	25 uL	30 uL
Instrument	Access Immunoassay system	DxI 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: Measurement Procedure Comparison and Bias Estimation Using Patient Samples– Third Edition

Summary of Studies:

Method Comparison: A method comparison study was performed to compare the Access OV Monitor assay on the DxI 9000 Access Immunoassay Analyzer to the predicate device. A total of one hundred fifty-two (152) samples falling within the measuring range of the Access OV Monitor assay were evaluated. The results of the within range method comparison study met the acceptance criteria of $R^2 \geq 0.90$ and slope 1.00 ± 0.09.

N	Concentration Range* (U/mL)	Slope	Slope 95% CI	Intercept	Intercept 95% CI	R^2
152	2.4 - 5001	0.98	0.97 – 0.99	-0.14	-0.38 – 0.13	1.00

*Range is Access 2 values

Imprecision: A study based on CLSI EP05-A3 performed on the DxI 9000 Access Immunoassay Analyzer tested multiple samples in triplicate in 2 runs per day for a minimum of 20 days. On the DxI 9000 Access Immunoassay Analyzer, the within-laboratory (total) % CV ranged from 2.6% to 6.1%, for OV Monitor concentrations > 15 U/mL and the within-laboratory SD of 0.2 for a sample concentration ≤ 15 U/mL was observed.

Concentration (U/mL)			Repeatability (Within-run)		Between-run		Between-day		Within-Laboratory (Total)	
Sample	N	Mean	SD	%CV	SD	%CV	SD	%CV	SD	%CV
Sample 1	120	5.5	0.1	1.7	0.1	1.6	0.2	3.4	0.2	4.1
Sample 2	120	54	1.6	2.9	0.0	0.0	1.2	2.2	2.0	3.6
Sample 3	120	89	1.5	1.6	1.7	1.9	1.2	1.3	2.5	2.8
Sample 4	120	524	9.4	1.8	5.8	1.1	8.7	1.7	14.0	2.7
Sample 5	120	1578	30.0	1.9	17.8	1.1	20.8	1.3	40.6	2.6
Sample 6	120	2837	94.9	3.3	23.3	0.8	131.2	4.6	163.7	5.8
Sample 7	120	3632	101.6	2.8	52.9	1.5	162.4	4.5	198.7	5.5
Sample 8	120	4489	128.1	2.9	28.4	0.6	239.4	5.3	273.0	6.1

Linearity: A verification study was performed to evaluate the linearity of the Access OV Monitor assay on the DxI 9000 Access Immunoassay Analyzer based on CLSI EP06-Ed2. The Access

OV Monitor assay is linear on the DxI 9000 Access Immunoassay Analyzer throughout the analytical measuring interval of approximately 2.0 – 5,000 U/mL.

Limit of Blank (LoB): The LoB for Access OV Monitor assay is 0.5 U/mL on DxI 9000 Access Immunoassay Analyzer.

Limit of Detection (LoD): The LoD estimate for the Access OV Monitor assay is 0.7 U/mL on DxI 9000 Access Immunoassay Analyzer.

Limit of Quantitation (LoQ): The maximum LoQ determined for the Access OV Monitor assay is 2.0 U/mL on DxI 9000 Access Immunoassay Analyzer.

Substantial Equivalence Comparison Conclusion

Beckman Coulter's Access OV Monitor assay on the DxI 9000 Access Immunoassay Analyzer is substantially equivalent to OV Monitor assay on the Access Immunoassay System (K023597) 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.