May 9, 2024

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

Re: K240403
Trade/Device Name: Access BR Monitor
Regulation Number: 21 CFR 866.6010
Regulation Name: Tumor-Associated Antigen Immunological Test System
Regulatory Class: Class II
Product Code: MOI
Dated: February 9, 2024
Received: February 9, 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

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)*

K240403

Device Name

Access BR Monitor

Indications for Use *(Describe)*

The Access BR Monitor assay is a paramagnetic particle, chemiluminescent immunoassay for the quantitative determination of CA 15-3 antigen levels in human serum and plasma (heparin) using the Access Immunoassay Systems. This device is indicated for use in the measurement of CA 15-3 antigen to aid in the management of breast cancer patients. Serial testing for CA 15-3 antigen concentrations should be used in conjunction with other clinical methods for monitoring breast 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 21 CFR 807.92.

510(k) Number: K240403 Date Prepared: April 29, 2024

Submitted By:
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Device Name:
Common Name: Immunoassay for the determination of CA 15-3 antigen
Trade Name: Access BR Monitor Reagents
Classification Name: Tumor-associated antigen immunological test system
Classification Regulation: (21 CFR 866.6010)

Predicate Device:
Device Name: Access BR Monitor
510(k) Numbers: k072612, k033036

Device Description

The Access BR Monitor assay, Access BR Monitor Calibrators, and the Access Immunoassay analyzers comprise the DxI 9000 Access Immunoassay Amalyzer for the quantitative determination of CA 15-3 antigen levels in human serum and plasma (heparin) using the DxI 9000 Access Immunoassay Analyzer.

Intended Use

The Access BR Monitor assay is a paramagnetic particle, chemiluminescent immunoassay for the quantitative determination of CA 15-3 antigen levels in human serum and plasma (heparin) using the Access Immunoassay Systems. This device is indicated for use in the measurement of CA 15-3 antigen to aid in the management of breast cancer patients. Serial testing for CA 15-3 antigen concentrations should be used in conjunction with other clinical methods for monitoring breast cancer.

Comparison of Technological Characteristics to the Predicate

Parameter	Access BR Monitor on Access 2 Immunoassay System Predicate – k072612	Access BR Monitor on DxI 9000 Access Immunoassay Analyzer
Intended use	The Access BR Monitor assay is a paramagnetic particle, chemiluminescent immunoassay for the quantitative determination of CA 15-3 antigen levels in human serum and plasma (heparin) using the Access Immunoassay Systems. This device is indicated for use in the measurement of CA 15-3 antigen to aid in the management of breast cancer patients. Serial testing for CA 15-3 antigen concentrations should be used in conjunction with other clinical methods for monitoring breast cancer.	Same
Analyte Measured	CA 15-3 antigen levels in human serum and plasma (heparin)	Same
Technology	Two-site immunoenzymatic ("sandwich") assay	Same
Format	Chemiluminescent	Same
Method	Automated	Same
Calibration	Utilizes a stored calibration curve	Same
Measuring Range	0.5 – 1,000 U/mL	0.8 – 1,000 U/mL
Substrate	Access Substrate	Lumi-Phos PRO Substrate
Instrument	Access 2 Immunoassay system;	DxI 9000 Access Immunoassay Analyzer

Standard/Guidance Document Referenced (if applicable):

These standards can be copied or found from regulatory submission reports:

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 Edition20 using Passing-Bablok regression and Pearson's correlation compared the Access 2 Immunoassay System and the DxI 9000 Access Immunoassay Analyzer.

N	Concentration Range* (U/mL)	Slope	Slope 95% CI	Intercept	Intercept 95% CI	Correlation Coefficient R
163	0.55 - 990	0.95	0.94 - 0.96	0.70	0.31 - 1.4	1.00

*Range is Access 2 values

Imprecision: The within-laboratory imprecision is ≤ 1.5 U/mL SD at concentrations < 15 U/mL and ≤ 10.0% CV at concentrations ≥ 15 u/mL. The results met the acceptance criteria and indicated that the imprecision of the Access BR Monitor assay is acceptable on DxI 9000 Access Immunoassay Analyzer.

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	126	4.2	0.1	2.0	0.1	2.8	0.0001	0.0	0.1	3.4
Sample 2	126	19	0.3	1.6	0.4	2.0	0.2	1.2	0.5	2.9
Sample 3	120	34	0.8	2.2	0.6	1.7	0.6	1.6	1.1	3.2
Sample 4	120	79	1.8	2.3	1.5	2.0	0.0	0.0	2.4	3.0
Sample 5	120	105	1.9	1.8	2.4	2.3	0.0	0.0	3.1	3.0
Sample 6	120	425	9.2	2.2	9.8	2.3	0.0	0.0	13.4	3.2
Sample 7	120	825	26.3	3.2	19.9	2.4	1.8	0.2	33.0	4.0

Linearity: The results of this study met the acceptance criterion, indicating that the Access BR Monitor assay is linear on the DxI 9000 Access Immunoassay Analyzer throughout the analytical measuring interval (0.8 – 1,000 U/mL).

Limit of Blank (LoB): The LoB estimate for BR Monitor was determined to be 0.1 U/mL on DxI 9000 Immunoassay Analyzer. The results of this study demonstrate that the BR Monitor assay met the acceptance criteria of 0.4 U/mL on DxI 9000 Access Immunoassay Analyzer.

Limit of Detection (LoD): The LoD estimate for the BR Monitor assay is 0.3 U/mL on DxI 9000 Immunoassay Analyzer. The results of this study demonstrate that the BR Monitor assay met the acceptance criteria of 0.5 U/mL on DxI 9000 Access Immunoassay Analyzer.

Limit of Quantitation (LoQ): The results provided demonstrate the 20% CV LoQ estimate for the BR Monitor assay to be 0.3 U/mL. The results provided demonstrate the LoQ at 20% within-laboratory imprecision estimate of the BR Monitor assay to be 0.8 U/mL on the DxI 9000 Immunoassay Analyzer.

Conclusion: Beckman Coulter's Access BR Monitor on the DxI 9000 Access Immunoassay Analyzer is substantially equivalent to the Access BR Monitor 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.