



February 16, 2024

Beckman Coulter, Inc
Neha Desai
Staff Quality and Regulatory Affairs
1000 Lake Hazeltine Drive
Chaska, Minnesota 55318

Re: K234005

Trade/Device Name: Access CK-MB
Regulation Number: 21 CFR 862.1215
Regulation Name: Creatine Phosphokinase/Creatine Kinase Or Isoenzymes Test System
Regulatory Class: Class II
Product Code: JHX
Dated: December 18, 2023
Received: December 19, 2023

Dear Neha Desai:

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,

Paula V. Caposino -S

Paula Caposino, Ph.D.
Acting Deputy Division Director
Division of Chemistry
and Toxicology 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)

K234005

Device Name

Access CK-MB

Indications for Use (Describe)

The Access CK-MB assay is a paramagnetic particle, chemiluminescent immunoassay for the quantitative determination of CK-MB levels in human serum and plasma using the Access Immunoassay Systems to aid in the diagnosis and treatment of myocardial infarction and muscle diseases such as progressive, Duchenne-type muscular dystrophy.

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.

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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 K234005

Submitted By:

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Common Name: CK-MB Enzyme Immunoassay

Trade Name: Access CK-MB

Classification Code: JHX

Classification Regulation: 21 CFR 862.1215

Predicate Device

Device Name: Access CK-MB

510(k) Numbers: K030012

Device Description

The Access CK-MB assay is a paramagnetic particle, chemiluminescent immunoassay for the quantitative determination of CK-MB levels in human serum and plasma using the Access Immunoassay Systems to aid in the diagnosis and treatment of myocardial infarction and muscle diseases such as progressive, Duchenne-type muscular dystrophy. The Access CK-MB assay is a two-site immunoenzymatic ("sandwich") assay. Patient sample is added to a reaction vessel with mouse monoclonal anti-human CK-MB antibody-alkaline phosphatase conjugate and paramagnetic particles coated with mouse monoclonal anti-human CK-BB. Human serum CK-MB binds to the anti-CK-MB conjugate and is immobilized on the paramagnetic particle coated with anti-CK-BB. The CK-MB in the human serum or plasma binds to the immobilized anti-CK-BB on the solid phase by the sub-unit B epitope (common to CK-BB and CK-MB isoforms), while the

mouse anti-CK-MB conjugate reacts specifically with the serum or the plasma CK-MB (no reaction with CK-MM or CK-BB isoforms).

After 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 CK-MB assay is a paramagnetic particle, chemiluminescent immunoassay for the quantitative determination of CK-MB levels in human serum and plasma using the Access Immunoassay Systems to aid in the diagnosis and treatment of myocardial infarction and muscle diseases such as progressive, Duchenne-type muscular dystrophy.

Comparison of Technological Characteristics to the Predicate (Assay)

Parameter	Access CK-MB Assay on Access® Immunoassay System (Predicate)	Access CK-MB Assay on Dxl 9000 Access® Immunoassay Analyzer
Intended use	The Access CK-MB assay is a paramagnetic particle, chemiluminescent immunoassay for the quantitative determination of CK-MB levels in human serum and plasma using the Access Immunoassay Systems to aid in the diagnosis and treatment of myocardial infarction and muscle diseases such as progressive, Duchenne-type muscular dystrophy.	Same
Technology	The Access CK-MB assay is a two-site immunoenzymatic (“sandwich”) assay. Patient sample is added to a reaction vessel with mouse monoclonal anti-human CK-MB antibody-alkaline phosphatase conjugate and paramagnetic particles coated with mouse monoclonal anti-human CK-BB.	Same
Solid Support	Paramagnetic Particles	Same
Detection System	Utilizes dioxetane-based chemiluminescent substrate; Measures light production from a chemiluminescent reaction.	Same
Calibration	Liquid calibrators prepared from buffered bovine serum albumin matrix with recombinant CK-MB at specified levels.	Same

Parameter	Access CK-MB Assay on Access® Immunoassay System (Predicate)	Access CK-MB Assay on Dxl 9000 Access® Immunoassay Analyzer
Sample Type	Serum and plasma	Same
Reference Interval	EDTA plasma: 0.5 ng/ml - 5.0 ng/ml Serum and Lithium heparin plasma: 0.6 ng/ml – 6.3 ng/ml	Serum, Lithium heparin and EDTA plasma: 0.6 ng/ml – 6.3 ng/ml
Measuring Range	0.1 - 300 ng/mL	0.2 - 300 ng/mL
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

CLSI EP28-A3c Defining, Establishing, and Verifying Reference Intervals in the Clinical Laboratory – Third Edition

CLSI EP35 Assessment of Equivalence of Suitability of Specimen Types for Medical Laboratory Measurement Procedures – First Edition

Summary of Studies

Method Comparison:

A study based on CLSI EP09c 3rd Edition, Measurement Procedure Comparison and Bias Estimation Using Patient Samples; Approved Guidelines, 3rd Edition compared the Access 2 Immunoassay System and the Dxl 9000 Access Immunoassay Analyzer.

N	Concentration Range* ng/mL	Slope	Slope 95% CI	Intercept	Intercept 95% CI	Correlation Coefficient R
146	[0.29 - 271]	1.04	1.03- 1.05	0.0066	-0.019 - 0.032	1.00

*Range is Access 2 values

Imprecision:

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

SD ≤ 0.04 ng/mL for values ≤ 0.5 ng/mL

CV ≤ 8.0% for values > 0.5 ng/mL

A study based on CLSI EP05-A3 performed on the DxI 9000 Access Immunoassay Analyzer tested multiple samples in duplicate in 2 runs per day for a minimum of 20 days.

Concentration ng/mL (µg/L)			Repeatability (Within-run)		Between-run		Between-day		Within-Laboratory (Total)	
Sample	N	Mean	SD	%CV	SD	%CV	SD	%CV	SD	%CV
Sample 1	80	0.2	0.01	5.2	0.01	3.4	0.003	1.9	0.01	6.5
Sample 2	80	9.2	0.2	2.2	0.2	2.6	0.00	0.0	0.3	3.4
Sample 3	80	54	1.1	2.0	1.1	2.0	0.5	1.0	1.6	3.0
Sample 4	80	120	3.0	2.5	1.6	1.4	1.3	1.1	3.6	3.0
Sample 5	80	220	4.5	2.0	2.9	1.3	1.3	0.6	5.4	2.5

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

Limit of Blank (LoB), Limit of Detection (LoD) and Limit of Quantitation (LoQ): 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 3 instruments over a minimum of 3 days. The LoD and LoQ studies included multiple reagent lots and 3 instruments over a minimum of 5 days.

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

Substantial Equivalence Comparison Conclusion

Beckman Coulter's Access CK-MB Assay on the DxI 9000 Access Immunoassay Analyzer is substantially equivalent to the Access CK-MB Assay on the Access 2 Immunoassay System (K030012) 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.