September 18, 2023

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

Re: K231832
Trade/Device Name: Access Myoglobin
Regulation Number: 21 CFR 866.5680
Regulation Name: Myoglobin Immunological Test System
Regulatory Class: Class II
Product Code: DDR
Dated: June 21, 2023
Received: June 22, 2023

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 (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,

Paula V. Caposino -S

Paula Caposino, Ph.D.
Acting Deputy 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

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)*
k231832

Device Name
Access Myoglobin

Indications for Use *(Describe)*
The Access Myoglobin assay is a paramagnetic particle, chemiluminescent immunoassay for the quantitative determination of myoglobin levels in human serum and plasma using the Access Immunoassay Systems to aid in the diagnosis of heart or renal disease.

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.

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 k231832

Submitter Name and Address:
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Trade Name: Access Myoglobin
Common Name: Myoglobin
Classification Regulation: 21 CFR 866.5680
Classification Product Code: DDR

Predicate Device:
Access Myoglobin
510(k) Number K021229

Device Description

The Access Myoglobin assay is a sandwich immunoenzymatic assay. The Access Myoglobin assay consists of the reagent pack and calibrators. Other items needed to run the assay include substrate and wash buffer. The Access Myoglobin assay reagent pack, Access Myoglobin 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 Myoglobin assay is a paramagnetic particle, chemiluminescent immunoassay for the quantitative determination of myoglobin levels in human serum and plasma using the Access Immunoassay Systems to aid in the diagnosis of heart or renal disease.

Comparison of Technological Characteristics to the Predicate (Assay)

System Attribute/Characteristic	Predicate Access Myoglobin assay (k021229) run on the Access 2 Immunoassay System	Access Myoglobin assay run on the DxI 9000 Access Immunoassay Analyzer Instrument
Intended Use/ Indications for Use	The Access Myoglobin assay is a paramagnetic particle, chemiluminescent immunoassay for the quantitative determination of myoglobin levels in human serum and plasma using the Access Immunoassay Systems.	Same
Assay Principles	The Access Myoglobin assay is a two-site immunoenzymatic ("sandwich") assay. A sample is added to a reaction vessel with mouse monoclonal anti-myoglobin-alkaline phosphatase conjugate, mouse monoclonal anti-myoglobin-biotin conjugate, and paramagnetic particles coated with goat anti-biotin.	Same
Solid Support	Paramagnetic Particles	Same
Detection System	Utilizes dioxetane-based chemiluminescent substrate; Measures light production from a chemiluminescent reaction	Same
Calibrators	Liquid calibrators prepared from buffered bovine protein matrix and human skeletal Myoglobin at various levels	Same
Sample Type	Serum/Plasma (heparin or EDTA)	Same
Measuring Range	1 – 4000 ng/mL	3.0 – 4000 ng/mL
Expected Results	Separate ranges for Heparin plasma/serum vs EDTA plasma	Same ranges
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
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 using Weighted Deming regression and Pearson's correlation compared the Access 2 Immunoassay System and the DxI 9000 Access Immunoassay Analyzer.

N	Concentration Range* (ng/mL)	Slope	Slope 95% CI	Intercept	Intercept 95% CI	R
155	8.2 – 3900	0.99	0.98 – 1.00	0.47	-0.10 – 1.0	1.00

*Range is Access 2 values

Imprecison: The assay was designed to have within-laboratory imprecision as listed below:
≤ 1.10 ng/mL (µg/L) SD at concentrations ≤ 11.0 ng/mL (µg/L)
≤ 10.0% CV at concentrations > 11.0 ng/mL (µg/L)
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.

ng/mL (µg/L)			Repeatability (Within-Run)		Between-Run		Between-Day		Within-Laboratory	
Sample	N	Mean	SD	%CV	SD	%CV	SD	%CV	SD	%CV
Sample 1	80	7.9	0.18	2.3	0.18	2.2	0.17	2.2	0.31	3.9
Sample 2	80	101	2.2	2.1	4.0	4.0	3.0	3.0	5.5	5.4
Sample 3	80	465	8.0	1.7	15.1	3.2	0.0	0.0	17.0	3.7
Sample 4	80	1763	35.0	2.0	57.5	3.3	0.1	0.0	67.3	3.8
Sample 5	80	2719	54.8	2.0	85.9	3.2	0.0	0.0	101.9	3.7

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)	3.0
Limit of Detection (LoD)	3.0
Limit of Quantitation (LoQ) ≤ 20% within-lab CV	3.0

Substantial Equivalence Comparison Conclusion

Beckman Coulter's Access Myoglobin assay on the DxI 9000 Access Immunoassay Analyzer is substantially equivalent to Myoglobin assay on the Access Immunoassay System (k021229) 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.