December 18, 2023

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

Re: K222881
Trade/Device Name: Access hsTnI
Regulation Number: 21 CFR 862.1215
Regulation Name: Creatine phosphokinase/creatine kinase or isoenzymes test system
Regulatory Class: Class II
Product Code: MMI
Dated: August 3, 2023
Received: August 3, 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 (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

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.

510(k) Number *(if known)*
k222881

Device Name
Access hsTnI

Indications for Use *(Describe)*
Access hsTnI is a paramagnetic particle, chemiluminescent immunoassay for the quantitative determination of cardiac troponin I (cTnI) levels in human serum and plasma using the DxI Access Immunoassay Analyzers to aid in the diagnosis of myocardial infarction (MI).

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 21 CFR 807.92(a)(1).

The assigned 510(k) number is k222881

Submitted By:
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Trade Name: Access hsTnI
Common Name: Troponin I Enzyme Immunoassay
Classification Regulation: 21 CFR 862.1215
Classification Product Code: MMI

Predicate Devices:
Access hsTnI, FDA 510(k) Number K172787

Device Description

The Access hsTnI assay is a sandwich immunoenzymatic assay. The Access hsTnI assay consists of the reagent pack and calibrators. Other items needed to run the assay include substrate and wash buffer. The Access hsTnI reagent pack, Access hsTnI 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

Access hsTnI is a paramagnetic particle, chemiluminescent immunoassay for the quantitative determination of cardiac troponin I (cTnI) levels in human serum and plasma using the DxI Access Immunoassay Analyzers to aid in the diagnosis of myocardial infarction (MI).

Comparison of Technological Characteristics to the Predicate (Assay)

Characteristic	Predicate Access hsTnI on Access 2 Immunoassay System	Access hsTnI for DxI 9000 Access Immunoassay Analyzer
Intended Use/ Indications for Use	Access hsTnI is a paramagnetic particle, chemiluminescent immunoassay for the quantitative determination of cardiac troponin I (cTnI) levels in human serum and plasma using the Access 2 Immunoassay Systems to aid in the diagnosis of myocardial infarction (MI).	Access hsTnI is a paramagnetic particle, chemiluminescent immunoassay for the quantitative determination of cardiac troponin I (cTnI) levels in human serum and plasma using the DxI Access Immunoassay Analyzers to aid in the diagnosis of myocardial infarction (MI).
Technology	Sandwich	Same
Format	Chemiluminescent	Same
Method	Automated	Same
Sample Type	Serum and lithium heparin plasma	Same
Analytical Measuring Range	2.0 pg/mL to 27,027 pg/mL	Same
Automated Dilution (Dilution Recovery)	Up to approximately 270,270 pg/mL	Same
Expected Results (Upper Reference Limit)	99th percentile of 17.5 pg/ mL with a 95% Confidence Interval (CI) of 12.6 – 20.7 pg/mL for plasma and 18.2 pg/mL with a 95% Confidence Interval (CI) of 13.1-23.1 pg/mL for serum.	Same
Precision	• ≤ 10% within-laboratory CV for concentrations ≥ 11.5 pg/mL • ≤ 1.15 pg/mL within laboratory SD for concentrations < 11.5 pg/mL	Same
Primary Reagent Materials	Mouse monoclonal anti-human cTnI antibody; detection is Sheep monoclonal anti-human cTnI	Same
Open Reagent Pack Stability	Stable at 2 to 10°C for 64 days after opening	Same
Reagent Pack configuration	Reagents ready to use and separated in a single reagent pack	Same
Assay Protocol File (APF)	hsTnI APF with no thermal algorithm	Same
Immunoassay Instrument	Access 2 Immunoassay system	DxI 9000 Access Immunoassay Analyzer
Substrate	Access Substrate	Lumi-Phos PRO substrate

Clinical performance: A study based on CLSI EP09c, 3rd Edition using Passing-Bablok regression and Pearson's correlation compared the Access 2 Immunoassay System and the DxI 9000 Access Immunoassay Analyzer. The results of the method comparison study met the acceptance criteria of slope 1.00 ± 0.10 and supports the equivalence of the Access hsTnI on DxI 9000 to the Access hsTnI on DxI 9000 Access Immunoassay Analyzer for both lithium heparin plasma and serum samples.

Imprecision: The within-laboratory (total) % CV ranged from 2.3% to 6.4% for serum samples and 1.7% to 4.4% for plasma samples, for hsTnI concentrations ≥ 11.5 pg/mL. The within-laboratory (total) SD ranged from 0.17 to 0.33 for serum samples and 0.17 to 0.40 for plasma samples with hsTnI concentrations < 11.5 pg/mL.

Linearity: This study shows that the acceptance criteria was met for non-linearity within ± 10% for values ≥11.5 pg/mL and ± 1.15 pg/mL for values < 11.5 pg/mL.

LoB/LoD: The data demonstrated the LoB estimate of the Access hsTnI is 0.5 pg/mL and the LoD estimate are 0.9 pg/mL (serum) and 0.8 pg/mL(plasma).

LoQ: The LoQ for Access hsTnI at ≤20% with-in lab CV was determined to be 1.0 pg/mL (serum) and 0.8 pg/mL (plasma).

Carryover: No clinically significant carryover for ≥95% of high samples tested up to 270,000 pg/mL (ng/L), based on a concentration shift of <3.5 pg/mL (ng/L) when testing a low sample (≤10 pg/mL [ng/L]).

Substantial Equivalence Comparison Conclusion

The information provided in this submission supports a substantial equivalence determination, and therefore 510(k) premarket notification clearance of the Access hsTnI on DxI 9000 Access Immunoassay Analyzer.