August 1, 2025

Beckman Coulter Inc.
Stephanie Garth
Principal of Regulatory Affairs
1000 Lake Hazeltine Drive
Chaska, Minnesota 55318

Re: K243483
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: June 18, 2025
Received: June 18, 2025

Dear Stephanie Garth:

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.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

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.
Deputy Director
Division of Chemistry
and Toxicology Devices
OHT7: Office of In Vitro Diagnostics
Office of Product Evaluation and Quality
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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)*
K243483

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 Unicel DxI Immunoassay Systems 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.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

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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.

510k Number: K243483

Submitter Name and Address:
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Date Prepared:
July 30, 2025

Device Name:
Proprietary / Trade Name: Access hsTnI
Common Name: Troponin I Enzyme Immunoassay
Classification Name: Immunoassay, Troponin Subunits
Classification Regulation: 21 CFR 862.1215
Classification Product Code: MMI

Predicate Devices:
Beckman Coulter, Inc. believes that the Access hsTnI run on the UniCel DxI 800 is substantially equivalent to the legacy Access 2 Immunoassay System improved Access hsTnI with a software upgrade to assist with washing efficiency. The following table provides a comparison of the technological characteristics of the Access hsTnI reagent on the predicate Access hsTnI versus the Unicel DxI 800 with and without the modifications.

Device Description:
The Access hsTnI is a two–site immunoenzymatic (“sandwich”) assay. Monoclonal anti–cTnI antibody conjugated to alkaline phosphatase is added to a reaction vessel along with a surfactant–containing buffer and sample. After a short incubation, paramagnetic particles coated with monoclonal anti–cTnI antibody are

added. The human cTnI binds to the anti–cTnI antibody on the solid phase, while the anti–cTnI antibody–alkaline phosphatase conjugate reacts with different antigenic sites on the cTnI molecules. 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:
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 Unicel DxI Immunoassay Systems to aid in the diagnosis of myocardial infarction (MI).

Substantial Equivalence Comparison:

Characteristic	Access hsTnI K230648- Predicate	Access hsTnI Candidate
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).	Similar
Assay Principle	Chemiluminescent	Same
Technology	Sandwich	Same
Test Systems	Automated immunoassay instrument	Same
Sample Type	Serum and lithium heparin plasma	Same
Sample Volume	55µl	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
Analytical Measuring Range	2.3 pg/mL to 27,027 pg/mL	Similar
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 lithium heparin plasma and 18.2 pg/mL with a 95% Confidence Interval (CI) of 13.1-23.1 pg/mL for serum.	Similar

Characteristic	Access hsTnI K230648- Predicate	Access hsTnI Candidate
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
Dilution factor/recovery Extended recovery range	1:5 up to >150,000 pg/mL New limitation statements related to carryover	Same

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 EP34 1st Edition – Establishing and Verifying an Extended Measuring Interval Through Specimen Dilution and Spiking

Method comparison: 239 samples (119 Lithium Heparin Plasma and 120 Serum) were analyzed across 3 UniCel DxI 800 instruments, Each sample was measured using the IVD Access hsTnI (Current Assay Protocol File (APF)) as well as the proposed Access hsTnI (Proposed APF). The first replicate result from each sample was utilized to fit a Passing-Bablok linear regression model. 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 UniCel DxI 800 instruments for both lithium heparin plasma and serum samples. The bias data support the reference intervals defined on the instruments have not changed appreciably from the commercialized product.

Imprecision: For UniCel DxI 800 instruments the within-laboratory (total) % CV ranged from 3% to 4%, for Access hsTnI concentrations ≥ 11.5 pg/mL. The within-laboratory (total) SD was 0.48 pg/mL for Access hsTnI concentration < 11.5 pg/mL.

Linearity: This study shows that the analysis of the data finds that across the UniCel DxI 800 instruments, and for each sample concentration range, the higher order (2nd or 3rd) term of the polynomial fit is non-significant ($p > 0.05$), and if significant, the fit of the polynomial regression demonstrating significance have ≤ 10% bias across the analytical measuring range.

LoB/LoD: The data demonstrated the LoB estimate of the Access hsTnI is 1.5 and the LoD estimate is 1.8 for serum and plasma.

LoQ: The LoQ for Access hsTnI at ≤20% with-in lab CV was determined to be 1.3 pg/mL (serum) and 1.2 (plasma).

Carryover and new dilution factors: The sponsor performed studies on the UniCel DxI 800 instruments to evaluate intra-assay carryover and included a limitation in the labeling describing the carryover observed. In the study, when a sample with cTnI > 150,000 pg/mL (ng/L) was tested on DxI 800 systems, intra-assay carryover was observed if an Access hsTnI was tested after a high cTnI sample. The extent of carryover observed was directly proportional to the cTnI concentration that was present in the high sample. In the studies, the estimated carryover was 3-5 pg/mL (ng/L) from a high sample at 270,000 pg/mL (ng/L) and 5-8 pg/mL (ng/L) from a high sample at 500,000 pg/mL (ng/L).

Substantial Equivalence Comparison Conclusion:
Beckman Coulter's Access hsTnI on the UniCel DxI 800 Immunoassay System is substantially equivalent to Access hsTnI on the predicate 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.