June 16, 2025

Beckman Coulter, Inc.
Mary Beth Tang
Senior Staff Regulatory Affairs
250 South Kraemer Boulevard
Brea, California 92870

Re: K242870
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: May 9, 2025
Received: May 9, 2025

Dear Mary Beth Tang:

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
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)*
k242870

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 Access 2 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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"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

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.

The assigned 510(k) number is K242870.

Submitted By:

Beckman Coulter, Inc.
250 S. Kraemer Boulevard
Brea, CA 92821

Contact Person:

Mary Beth Tang
Senior Staff Regulatory Affairs
Telephone: 714-961-3728
Email: mbtang@beckman.com

Date of Preparation:

June 16, 2025

Device Name(s):

Proprietary Name:	Access hsTnI
Common Name:	Troponin I Enzyme Immunoassay
Classification Name:	Immunoassay Method, Troponin Subunit
Class:	Class II
Regulation Number:	21 CFR 862.1215
Product Code:	MMI

Predicate Device:

Candidate	Predicate	Manufacturer	Predicate Docket
Access hsTnI	Access hsTnI	Beckman Coulter, Inc.	K230648

Device Description:

The Access hsTnI assay 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 Access 2 Immunoassay Systems to aid in the diagnosis of myocardial infarction (MI).

Substantial Equivalence Comparison:

Characteristic	Access hsTnI Predicate (K230648)	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).	Same
Assay Principle	Chemiluminescent	Same
Technology	Sandwich	Same
Test Systems	Automated immunoassay instrument	Same
Sample Type	Serum and lithium heparin plasma	Same
Measuring Range	2.0 pg/mL to 27,027 pg/mL	Same
Extended Range	1:5 dilution factor and limitation statement related to carryover	Same
Precision	Within-laboratory SD ≤1.15 pg/mL for levels <11.5 pg/mL; within-laboratory CV ≤10% for levels ≥11.5 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 lithium heparin plasma; 99th percentile of 18.2 pg/mL with a 95% CI of 13.1 – 23.1 pg/mL for serum.	Same
Primary Reagent Materials	Mouse monoclonal anti-human cTnI antibody; detection is Sheep monoclonal anti-human cTnI	Same
Reagent Pack Configuration	Reagents ready to use and separated in a single reagent pack	Same
Open Pack Stability	Stable at 2 to 10°C for 64 days after opening	Same
Reaction Substrate	Access Substrate	Same
Assay Protocol File (APF)	Access 2 hsTnI APF with O-command wash sequence	Same
Instrument Platforms	Access 2 Immunoassay System	DxC 500i Clinical Analyzer

Comparison Testing:

Substantial equivalence between the Access hsTnI assay on the immunoassay module of the DxC 500i Clinical Analyzer and the Access hsTnI assay on the Access 2 Immunoassay System was demonstrated through clinical and non-clinical analytical studies conducted in accordance with the following the standards and guidance documents:

- 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 EP09-ED3: Measurement Procedure Comparison and Bias Estimation Using Patient Samples– Third Edition
- Assay Migration Studies for In-Vitro Diagnostics Devices, Guidance for Industry and Staff, April, 2013

Summary of Performance Data:

Platform Equivalency by Sample Type

The Access hsTnI IFU states that serum and lithium heparin plasma sample types should not be used interchangeably; as such, BEC conducted a cross-platform equivalency study for each sample type independently. The study design evaluated the performance of multiple Access 2-DxC 500i instrument pairs using unique donor samples for each sample type. The test sample sets spanned the assay measuring range (2.0 – 27,027 pg/mL). The results of the platform equivalency study met the acceptance criteria of slope 1.00 ± 0.10. The Passing-Bablok analysis from a representative DxC 500i-versus-Access 2 instrument pair is summarized below.

Sample Type	Concentration Range (pg/mL)	N	Slope	Slope 95% CI	Intercept (pg/mL)	Correlation Coefficient (r)
Serum	2.06 – 22,781	106	1.001	0.976 – 1.020	-0.184	0.999
Plasma	2.25 – 26,379	122	0.997	0.978 – 1.016	0.560	0.999

Clinical performance

Method comparison studies were performed two external tests sites and one internal test site using three DxC 500i Clinical Analyzers and two Access 2 instruments. Each site evaluated more than 200 discrete lithium heparin plasma samples containing hsTnI concentrations spanning the analytical measuring range of the assay. Samples were evaluated over a minimum of three days in single replicates. The study utilized three reagent lots and one calibrator lot across the three test sites. The results of the method comparison study met the acceptance criteria of slope 1.00

± 0.10 and r ≥ 0.90 to demonstrate the equivalence of the Access hsTnI assay on DxC 500i to the Access hsTnI assay on Access 2.

Imprecision

The results of the CLSI EP05-A3 study on the DxC 500i analyzer met the acceptance criteria of a total (within-laboratory) imprecision ≤ 1.15 pg/mL at a troponin level less than 11.5 pg/mL, and ≤10.0% at a troponin level ≥ 11.5 pg/mL. For troponin concentrations < 11.5 pg/mL, the observed within-laboratory (total) SD ranged from 0.3 to 0.5 pg/mL for serum samples, and 0.3 to 0.5 pg/mL for plasma samples. For troponin concentrations ≥ 11.5 pg/mL, the observed within-laboratory (total) % CV ranged from 2.3% to 5.8% for serum samples, and 5.0% to 7.0% for plasma samples.

Linearity

The CLSI EP6-A2 study results met the acceptance criteria for non-linearity within ± 1.15 pg/mL for values < 11.5 pg/mL and ± 10% for values ≥ 11.5 pg/mL, thus verifying linearity across the Access hsTnI measuring range on the DxC 500i analyzer.

Detection Capability (LoB/LoD/LoQ)

The CSLI EP17-A2 study results on multiple DxC 500i analyzers met the acceptance criteria for the Access TnI assay LoB/LoD to be < 4.0 pg/mL, LoQ ≤ 5.0 pg/mL at a 20% within-lab CV, and LoQ ≤ 11.5 pg/mL at a 10% within-lab CV. Using plasma as the representative sample matrix, the largest observed estimates were 0.2 pg/mL for LoB and 1.0 pg/mL for LoD; the largest observed estimates for LoQ were 1.0 pg/mL at ≤ 20% CV and 1.3 pg/mL at ≤ 10% CV.

Carryover

The sponsor performed studies on DxC 500i 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 a DxC 500i system, 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). For inter-assay carryover, which occurs when a high cTnI sample is tested on an assay other than hsTnI, performance, representative data for inter-assay carryover indicates the potential magnitude of carryover from samples at 27,000 pg/mL is expected to be < 3.5 pg/mL, but can be as large as 77.8 pg/mL for troponin concentrations above 1,000,000 pg/mL.

Substantial Equivalence Conclusion

The performance data presented in this submission demonstrates that the Beckman Coulter Access hsTnI assay on the DxC 500i Clinical Analyzer is substantially equivalent to predicate Access hsTnI on the Access 2 Immunoassay System and continues to be safe and effective in its Intended Use.