



September 21, 2026

Beckman Coulter, Inc.
Beth Davis
Staff Regulatory Affairs
1000 Lake Hazeltine Dr.
Chaska, Minnesota 55318

Re: K262109
Trade/Device Name: Access NT-proBNP
Regulation Number: 21 CFR 862.1117
Regulation Name: B-type Natriuretic Peptide Test System
Regulatory Class: Class II
Product Code: NBC
Dated: June 23, 2026
Received: June 23, 2026

Dear Beth Davis:

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 Management System Regulation (QMSR) (21 CFR Part 820), which includes, but is not limited to, ISO 13485 clause 7.3 (Design controls), ISO 13485 clause 8.3 (Nonconforming product), ISO 13485 clause 8.5.2 (Corrective action), and ISO 13485 clause 8.5.3 (Preventative action). Please note that regardless of whether a change requires premarket review, the QMSR requires device manufacturers to review and approve changes to device design and production (ISO 13485 clause 7.3 and ISO 13485 clause 7.5) and document changes and approvals in the Medical Device File (ISO 13485 clause 4.2.3).

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 Management System Regulation (QMSR) (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
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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)

K262109

Device Name

Access NT-proBNP

Indications for Use (Describe)

The Access NT-proBNP assay is a paramagnetic particle, chemiluminescent immunoassay for the quantitative determination of N-terminal pro B-type natriuretic peptide levels in human serum and plasma using the automated Access Immunoassay Analyzers to aid in the following:

1. Diagnosis of patients suspected of having acute heart failure in the Emergency Department
2. Assessment of heart failure severity
3. Risk stratification of patients with heart failure
4. Risk stratification of patients with acute coronary syndrome

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 SMDA 1990 and 21 CFR 807.92.

510(k) Number: K262109

Date Prepared: August 25, 2026

Submitter Name and Address

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Chaska, MN 55318

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Trade Device Name: Access NT-proBNP
Common Name: test, natriuretic peptide
Classification name: B-Type natriuretic peptide test system
Classification Regulation: 21 CFR 862.1117
Classification Product Code: NBC
Predicate Device: Access NT-proBNP – K232164

Device Description

The Access NT-proBNP assay is a paramagnetic particle, chemiluminescent immunoassay for the quantitative determination of N-terminal pro B-type natriuretic peptide levels in human serum and plasma using the automated Access Immunoassay Analyzers to aid in the following:

- 1) Diagnosis of patients suspected of acute heart failure in the Emergency Department
- 2) Assessment of heart failure severity
- 3) Risk stratification of patients with heart failure
- 4) Risk stratification of patients with acute coronary syndrome

The Access NT-proBNP is a two-site immunoenzymatic (sandwich) assay. Paramagnetic particles coated with monoclonal anti-NT-proBNP antibody and monoclonal anti-NT-proBNP antibody conjugated to alkaline phosphatase are added to a reaction vessel along with a surfactant-containing buffer and serum or plasma sample. The human NT-proBNP binds to the anti-NT-proBNP antibody on the solid phase, while the anti-NT-proBNP antibody-alkaline phosphatase conjugate reacts with a different antigenic site on the NT-proBNP molecule. 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.

Other items required for use with the assay include calibrators, Access Substrate, and wash buffer. The Access NT-proBNP reagent packs, Access NT-proBNP Calibrators, Access Wash Buffer II, and Access Substrate are designed for use on the Access Immunoassay Analyzers in a clinical laboratory setting.

Intended Use

The Access NT-proBNP assay is a paramagnetic particle, chemiluminescent immunoassay for the quantitative determination of N-terminal pro B-type natriuretic peptide levels in human serum and plasma using the automated Access Immunoassay Analyzers to aid in the following:

1. Diagnosis of patients suspected of having acute heart failure in the Emergency Department
2. Assessment of heart failure severity
3. Risk stratification of patients with heart failure
4. Risk stratification of patients with acute coronary syndrome

Table 1: Device Comparison

Device Characteristics	Candidate Device Access NT-proBNP on Access 2 Immunoassay System	Predicate Device Access NT-proBNP on Dxl 9000 Immunoassay Analyzer (K232164)	Comment
Reference Number	C71977	C71977	Same
Intended Use / Indications for Use	Rx ONLY For <i>in vitro</i> diagnostic use only. The Access NT-proBNP assay is a paramagnetic particle, chemiluminescent immunoassay for the quantitative determination of N-terminal pro B-type natriuretic peptide levels in human serum and plasma using the automated Access Immunoassay Analyzers to aid in the following: 1. diagnosis of patients suspected of having acute heart failure in the Emergency Department	Rx ONLY For <i>in vitro</i> diagnostic use only. The Access NT-proBNP assay is a paramagnetic particle, chemiluminescent immunoassay for the quantitative determination of N-terminal pro B-type natriuretic peptide levels in human serum and plasma using the automated Dxl Access Immunoassay Analyzers to aid in the following: 1. diagnosis of patients suspected of having acute heart failure in the Emergency Department	Similar

Device Characteristics	Candidate Device Access NT-proBNP on Access 2 Immunoassay System	Predicate Device Access NT-proBNP on Dxl 9000 Immunoassay Analyzer (K232164)	Comment
	2. assessment of heart failure severity 3. risk stratification of patients with heart failure 4. risk stratification of patients with acute coronary syndrome	2. assessment of heart failure severity 3. risk stratification of patients with heart failure 4. risk stratification of patients with acute coronary syndrome	
Analyte Measured	NT-proBNP	NT-proBNP	Same
Antibody	Monoclonal anti-NT-proBNP	Monoclonal anti-NT-proBNP	Same
Sample Type	Human Serum and Plasma (Lithium Heparin and EDTA)	Human Serum and Plasma (Lithium Heparin and EDTA)	Same
Method	Automated Assay	Automated Assay	Same
	The Access NT-proBNP assay is used in association with the automated Access 2 Immunoassay System	The Access NT-proBNP assay is used in association with the automated Dxl Access Immunoassay Analyzer	Different
Format	Chemiluminescent	Chemiluminescent	Same
Assay Principle	Sandwich	Sandwich	Same
Measuring Range	10.0 ng/L – 35,000 ng/L (pg/mL)	10.0 ng/L – 35,000 ng/L (pg/mL)	Same
Traceability	The Access NT-proBNP Calibrator is traceable to manufacturer's working calibrators. Traceability process is based on EN ISO 17511	The Access NT-proBNP Calibrator is traceable to manufacturer's working calibrators. Traceability process is based on EN ISO 17511	Same
High Dose Hook Effect	No high dose hook effect observed up to 400,000 ng/L (pg/mL)	No high dose hook effect observed up to 400,000 ng/L (pg/mL)	Same
Reagent Storage and Stability	Access NT-proBNP Reagent Stability		Same
	Unopened at 2 -10°C	Up to stated Expiration Date	
	After Opening at 2-10°C	61 days	
	On analyzer	61 days	
	Access NT-proBNP Reagent Stability		
	Unopened at 2 -10°C	Up to stated Expiration Date	
	After Opening at 2-10°C	61 days	
	On analyzer	61 days	

Standard /Guidance Document Referenced

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 – 2nd Edition

EP09 3rd Edition – Measurement Procedure Comparison and Bias Estimation Using Patient Samples

Summary of Analytical Studies

Imprecision

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

- ≤ 4.0 ng/L (pg/mL) SD at concentrations ≤ 50 ng/L (pg/mL)
- $\leq 8.0\%$ CV at concentrations > 50 ng/L (pg/mL)

A study based on CLSI EP05-A3 performed on the Access 2 Immunoassay System tested multiple samples in duplicate in 2 runs per day for 20 days.

Table 2: Access NT-proBNP Imprecision

Sample	N	Mean (ng/L)	Repeatability (Within Run)		Between Run		Between Day		Within Laboratory Precision	
			SD (ng/L)	%CV	SD (ng/L)	%CV	SD (ng/L)	%CV	SD (ng/L)	%CV
Sample 1	80	40	1.9	4.8	1.1	2.8	1.6	3.9	2.7	6.8
Sample 2	80	139	3.2	2.3	3.3	2.4	2.9	2.1	5.4	3.9
Sample 3	80	334	8.7	2.6	2.9	0.9	2.5	0.8	9.5	2.8
Sample 4	80	464	10.0	2.2	6.3	1.3	5.6	1.2	13.0	2.8
Sample 5	80	1,891	54.1	2.9	0.1	0.0	26.8	1.4	60.3	3.2
Sample 6	80	8,279	165.5	2.0	95.6	1.2	84.4	1.0	208.9	2.5
Sample 7	80	22,931	507.6	2.2	1.5	0.0	337.0	1.5	609.3	2.7

High Dose Hook Effect

The study was performed using samples containing increasing concentrations of NT-proBNP antigen in a range greater than $> 400,000$ ng/L exceeding the dose of the S6 Calibrator. Access NT-proBNP assay has no high dose hook effect observed up to 400,000 ng/L.

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 Access 2 Immunoassay System following CLSI EP17-A2, *Evaluation of Detection Capability for Clinical Laboratory Measurement Procedures; Approved Guideline – Second Edition*. The LoB study included multiple reagent lots and 3 instruments for 3 days. The LoD and LoQ studies included multiple reagent lots and 3 instruments up to 5 days.

Table 3: Access NT-proBNP LoB, LoD and LoQ

	Maximum Observed Result	Design Criteria
	ng/L (pg/mL)	ng/L (pg/mL)
Limit of Blank (LoB)	1.8	<10.0
Limit of Detection (LoD)	3.5	≤10.0
Limit of Quantitation (LoQ) ≤ 20% within-lab CV	3.5	≤10.0

Linearity

A study based on CLSI EP06-Ed23 performed on the Access 2 Immunoassay System determined the assay demonstrated linearity across the measuring interval.

Matrix Comparison

A sample type comparison study was performed on the Access NT-proBNP assay. The study included fifty eight (58) matched serum, lithium heparin and EDTA plasma samples spanning the assay measuring range that were analyzed in replicates of two (2). The results of the study demonstrate all sample types are suitable for use on the Access NT-proBNP assay.

Method Comparison

A study based on CLSI EP09c, 3rd Edition compared this assay with Access NT-proBNP on Dxl 9000 Access Immunoassay Analyzers. Results support the equivalence of the Access NT-proBNP assay on Access 2 Immunoassay System to that of the Access NT-proBNP assay on Dxl 9000 Access Immunoassay Analyzer.

Table 4: Regression Statistics of Access NT-proBNP Access 2 vs Dxl 9000

N	Concentration Range (ng/L)*	Slope	Slope 95% CI	Intercept	Intercept 95% CI	Correlation Coefficient R
327	12.6 - 34397.4	0.99	[0.98,1.00]	-1.62	-3.25 - -0.21	1.00

*Concentration range represents Access Dxl 9000 values

Conclusion

This submission provides data to ensure that the Access NT-proBNP assay is safe and effective for the stated intended use and is substantially equivalent to the cleared predicate device.