May 4, 2023

Abbott Laboratories Diagnostics Division
Judi Wallach
Regulatory Affairs Project Manager
Dept. 9AA, Building CP01-2, 100 Abbott Park Road
Abbott Park, IL 60064

Re: K230994
Trade/Device Name: Alinity i STAT High Sensitivity Troponin-I
Regulation Number: 21 CFR 862.1215
Regulation Name: Creatine Phosphokinase/Creatine Kinase Or Isoenzymes Test System
Regulatory Class: Class II
Product Code: MMI
Dated: April 6, 2023
Received: April 7, 2023

Dear Judi Wallach:

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 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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K230994

Device Name
Alinity i STAT High Sensitivity Troponin-I

Indications for Use *(Describe)*
The Alinity i STAT High Sensitivity Troponin-I assay is a chemiluminescent microparticle immunoassay (CMIA) used for the quantitative determination of cardiac troponin I (cTnI) in human plasma (lithium heparin) on the Alinity i system.

The Alinity i STAT High Sensitivity Troponin-I assay is to be used as an 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.

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510(k) Summary

This summary of the 510(k) safety and effectiveness information is being submitted in accordance with the requirements of the Federal Food, Drug, and Cosmetic Act and 21 CFR 807.92.

I. 510(k) Number

K230994

II. Applicant Name

Date summary prepared: May 3, 2023

Abbott Laboratories Diagnostics Division
Dept. 9AA, CP01-2
100 Abbott Park Road
Abbott Park, IL 60064

Primary contact person for all communications:

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Julian Braz, Abbott Laboratories Diagnostics Division, Director, Regulatory Affairs
Telephone Number: (224) 330-9230

III. Device Name

Alinity i STAT High Sensitivity Troponin-I

Reagents

Trade Name: Alinity i STAT High Sensitivity Troponin-I
Device Classification: Class II
Classification Name: Creatine phosphokinase/creatine kinase or isoenzymes test system
Governing Regulation: 862.1215

Code: MMI

IV. Predicate Device

Alinity i STAT High Sensitivity Troponin-I (K202525)

V. Intended Use of the Device

The Alinity i STAT High Sensitivity Troponin-I assay is a chemiluminescent microparticle immunoassay (CMIA) used for the quantitative determination of cardiac troponin I (cTnI) in human plasma (lithium heparin) on the Alinity i system.

The Alinity i STAT High Sensitivity Troponin-I assay is to be used as an aid in the diagnosis of myocardial infarction (MI).

VI. Description of Device

The Alinity i STAT High Sensitivity Troponin-I Reagent Kit contains:

- **Microparticles:** 1 bottle (6.6 mL per 100 test cartridge / 33.8 mL per 600 test cartridge). Anti-troponin I (mouse, monoclonal) coated microparticles in TRIS buffer with protein (bovine) stabilizer. Minimum concentration: 0.035% solids. Preservative: ProClin 300.
- **Conjugate:** 1 bottle (6.1 mL per 100 test cartridge / 33.8 mL per 600 test cartridge). Anti-troponin I (mouse-human chimeric, monoclonal) acridinium-labeled conjugate in MES buffer with protein (bovine) stabilizer and human IgG. Minimum concentration: 0.1 mg/L. Preservative: ProClin 300.

Principles of the Procedure

The Alinity i STAT High Sensitivity Troponin-I assay is an automated, two-step immunoassay for the quantitative determination of cTnI in human plasma (lithium heparin) using CMIA technology.

Sample and anti-troponin I antibody-coated paramagnetic microparticles are combined and incubated. The cTnI present in the sample binds to the anti-troponin I coated microparticles. The mixture is washed. Anti-troponin I acridinium-labeled conjugate is added to create a reaction mixture and incubated. Following a wash cycle, Pre-Trigger and Trigger Solutions are added.

The resulting chemiluminescent reaction is measured as a relative light unit (RLU). There is a direct relationship between the amount of cTnI in the sample and the RLU detected by the system optics.

VII. Comparison of Technological Characteristics

The Alinity i STAT High Sensitivity Troponin-I assay (subject device) utilizes a CMIA methodology for the quantitative *in vitro* determination of cTnI and is intended for use on the Alinity i system.

The similarities and differences between the subject device and the predicate device are presented in the following table.

Characteristics	**Cleared Predicate Device: Alinity i STAT High Sensitivity Troponin-I (K202525)**	**Subject Device: Alinity i STAT High Sensitivity Troponin-I**
General Device Characteristic Similarities		
Intended Use and Indications for Use	The Alinity i STAT High Sensitivity Troponin-I assay is a chemiluminescent microparticle immunoassay (CMIA) used for the quantitative determination of cardiac troponin I (cTnI) in human plasma (lithium heparin) on the Alinity i system. The Alinity i STAT High Sensitivity Troponin-I assay is to be used as an aid in the diagnosis of myocardial infarction (MI).	Same
Specific Analyte Detected	cTnI	Same
Methodology	CMIA	Same
General Device Characteristic Differences		
Sample Dilution Procedures	Not applicable (N/A) – Sample dilutions are not recommended for the assay.	Automated dilution (1:30) Manual dilution (1:30)
Reportable Interval (ng/L, pg/mL)	Analytical measuring interval (AMI) = 2.7 – 3600.0 Extended measuring interval (EMI) = N/A Reportable interval = N/A	AMI = 2.7 – 3600.0 EMI = 3600.0 – 60,000.0 Reportable interval = 2.7 – 60,000.0

VIII. Performance Summary

A. Dilution Recovery

A study was performed based on guidance from Clinical and Laboratory Standards Institute (CLSI) EP34, 1st ed.[*] Samples were prepared by volumetrically spiking lithium heparin plasma with purified recombinant human cardiac troponin IC complex. For automated dilution (performed by the Alinity i instrument at 1:30), each sample was tested in replicates of 5 on 3 separate runs using one reagent lot and 3 instruments. For manual dilution, 2 technicians each prepared 3 separate 1:30 manual dilutions of the same samples and tested each dilution on a separate run using one reagent lot and 2 instruments. For samples up to 60,000.0 ng/L, dilution recovery ranged from 98.6% to 115.6% for automated dilution and 102.6% to 119.9% for manual dilution.

IX. Conclusion Drawn from Nonclinical Laboratory Studies and Clinical Performance

The results presented in this Special 510(k) demonstrate that the performance of the subject device (Alinity i STAT High Sensitivity Troponin-I with automated and manual dilution) is substantially equivalent to the performance of the predicate device (Alinity i STAT High Sensitivity Troponin-I, K202525).

There is no known potential adverse effect to the operator when using this *in vitro* device according to the Alinity i STAT High Sensitivity Troponin-I reagent package insert instructions.

[*] Clinical and Laboratory Standards Institute (CLSI). *Establishing and Verifying an Extended Measuring Interval Through Specimen Dilution and Spiking*. 1st ed. CLSI Guideline EP34. Wayne, PA: CLSI; 2018.