June 5, 2023

Abbott Laboratories
Melissa Vaughan
Director, Regulatory Affairs
1915 Hurd Drive
Irving, Texas 75038

Re: K230937
Trade/Device Name: Alinity i Total β-hCG Reagent Kit, GLP systems Track
Regulation Number: 21 CFR 862.1155
Regulation Name: Human chorionic gonadotropin (HCG) test system
Regulatory Class: Class II
Product Code: DHA, JJE, JQP
Dated: March 31, 2023
Received: April 3, 2023

Dear Melissa Vaughan:

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,

Marianela Perez-torres -S

Marianela Perez-Torres, Ph.D.
Acting 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)*
K230937

Device Name
GLP systems Track; Alinity i Total b-hCG Reagent Kit

Indications for Use *(Describe)*

GLP systems Track:

The GLP systems Track is a modular laboratory automation system designed to automate pre-analytical and post-analytical processing, including sample handling, in order to automate sample processing in clinical laboratories. The system consolidates multiple analytical instruments into a unified workflow.

Alinity i Total β-hCG Reagent Kit:

The Alinity i Total β-hCG assay is a chemiluminescent microparticle immunoassay (CMIA) used for the quantitative and qualitative determination of beta-human chorionic gonadotropin (β-hCG) in human serum and plasma for the early detection of pregnancy on the Alinity i analyzer.

Alinity i system:

The Alinity i System is a fully automated analyzer allowing random and continuous access, as well as priority and automated retest processing using chemiluminescent microparticle immunoassay (CMIA) technology. CMIA technology is used to determine the presence of antigens, antibodies, and analytes in samples.

Alinity ci-series:

The Alinity ci-series is intended for in vitro diagnostic use only.

The Alinity ci-series is a System comprised of individual Alinity i or Alinity c analyzers/processing modules that may be arranged into individual or multimodule configurations including up to four Alinity i processing modules, up to four Alinity c processing modules, or a combination of up to four of Alinity i and Alinity c processing modules with a shared system control module to form a single workstation.

The Alinity c System is a fully automated, random/continuous access, clinical chemistry analyzer intended for the in vitro determination of analytes in body fluids.

The Alinity i System is a fully automated analyzer allowing random and continuous access, as well as priority and automated retest processing using chemiluminescent microparticle immunoassay (CMIA) technology. CMIA technology is used to determine the presence of antigens, antibodies, and analytes in samples.

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 the 510(k) safety and effectiveness information is being submitted in accordance with the requirements of Safe Medical Device Act of 1990 and 21 CFR § 807.92.

I. 510(k) Number

K230937

II. Applicant Name

Abbott Laboratories
1915 Hurd Drive
Irving, TX 75038

Primary contact person for all communications:

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Date Summary Prepared: June 05, 2023

III. Device Name

GLP systems Track

Device Classification: Class I
Classification Name: Discrete photometric chemistry analyzer for clinical use.
Governing Regulation: 862.2160
Product Code: JJE

Device Classification: Class I
Classification Name: Calculator/data processing module for clinical use.
Governing Regulation: 862.2100
Product Code: JQP

Alinity i Total β-hCG Reagent Kit

Device Classification: Class II
Classification Name: Human chorionic gonadotropin (HCG) test system
Governing Regulation: 862.1155
Product Code: DHA

IV. Predicate Device

GLP systems Track (K213486)

V. Device Description

A. GLP systems Track

The GLP systems Track is a modular laboratory automation system (LAS) used to perform multiple pre-analytical and post-analytical steps to automate sample preparation and distribution processes in clinical laboratories. These processes include bar code identification of samples, centrifugation, aliquoting of samples, decapping of samples, transport of samples between processes (modules), delivery of samples to 1 or more Abbott and Third Party commercially available laboratory analyzer(s), capping of samples, and storage of samples. Due to the modular nature of the LAS, customers may select modules and configurations to fit their laboratory needs.

The GLP systems Track was previously cleared under K213486 with the purpose of using the laboratory automation system with clinical laboratory analyzers such as Alinity c system.

VI. Intended Use of the Device

GLP Systems Track

The GLP systems Track is a modular laboratory automation system designed to automate pre-analytical and post-analytical processing, including sample handling, in order to automate sample processing in clinical laboratories. The system consolidates multiple analytical instruments into a unified workflow.

Alinity i Total β-hCG Reagent Kit

The Alinity i Total β-hCG assay is a chemiluminescent microparticle immunoassay (CMIA) used for the quantitative and qualitative determination of beta human chorionic gonadotropin (β-hCG) in human serum and plasma for the early detection of pregnancy on the Alinity i analyzer.

Alinity i System

The Alinity i System is a fully automated analyzer allowing random and continuous access, as well as priority and automated retest processing using chemiluminescent microparticle immunoassay (CMIA) technology. CMIA technology is used to determine the presence of antigens, antibodies, and analytes in samples.

Alinity ci-series

The Alinity ci-series is intended for in vitro diagnostic use only.

The Alinity ci-series is a System comprised of individual Alinity i or Alinity c analyzers/processing modules that may be arranged into individual or multimodule configurations including up to four Alinity i processing modules, up to four Alinity c processing modules, or a combination of up to four of Alinity i and Alinity c processing modules with a shared system control module to form a single workstation.

The Alinity c System is a fully automated, random/continuous access, clinical chemistry analyzer intended for the in vitro determination of analytes in body fluids.

The Alinity i System is a fully automated analyzer allowing random and continuous access, as well as priority and automated retest processing using chemiluminescent microparticle immunoassay (CMIA) technology. CMIA technology is used to determine the presence of antigens, antibodies, and analytes in samples.

VII. Comparison of Technological Characteristics

The similarities and differences between the subject device and the predicate device are presented in the following table. There is no difference between the subject and predicate devices' indications for use.

Comparison of Subject Device (GLP systems Track) to Predicate Device (GLP systems Track)

Characteristics	Subject Device: GLP systems Track (Product Codes, JJE, JQP)	Predicate Device: GLP systems Track (Product Codes JJE, JQP) (K213486)
Intended Use/Indications for Use	The GLP systems Track is a modular laboratory automation system designed to automate pre-analytical and post-analytical processing, including sample handling, in order to automate sample processing in clinical laboratories. The system consolidates multiple analytical instruments into a unified workflow.	Same
Principle of Analyte Detection	An analyzer's detection method remains the same when interfaced to the GLP systems Track.	Same
Sample Containers	Primary tubes and secondary aliquot tubes.	Same
Sample Aspiration	Directly from tube presented to the aspiration point by the GLP systems Track.	Same
Sample Loading	GLP systems Track Input/Output Module (IOM) accepts samples loaded into sample racks. The BulkLoader Module accepts samples loaded into the bin. Samples may also be loaded directly into any analyzers that support local sample loading.	Same
Sample Pre-Analytics	Centrifugation: GLP systems Track automatically centrifuges sample tubes. Samples may also be manually centrifuged by lab personnel prior to loading onto the system.	Same
	Decapping: GLP systems Track automatically decaps sample tubes. Samples may also be manually decapped by lab personnel prior to loading onto the system.	
	Aliquoting:	

Characteristics	Subject Device: GLP systems Track (Product Codes, JJE, JQP)	Predicate Device: GLP systems Track (Product Codes JJE, JQP) (K213486)
	GLP systems Track automatically aliquots samples from the primary sample to bar coded secondary tubes.	
	Recapping: GLP systems Track automatically recaps sample tubes. Samples may also be manually recapped by lab personnel prior to loading onto system.	
	Storage: GLP systems Track automatically stores sample tubes in temperature-controlled storage. Samples may also be returned to IOM for lab personnel to manually store samples in lab.	
Sample Transport	GLP systems Track transports samples via CARs identified on the system by near-field communication (NFC) tags. Samples may also be manually transported by lab personnel to analyzers.	Same
Sample Identification	GLP systems Track reads sample bar codes and electronically communicates sample ID (SID) to some analyzers. The analyzer reads sample bar codes for samples loaded directly onto the analyzer or for samples transferred in a rack to the analyzer from the Laboratory Automation System (LAS).	Same
Test Orders	Unidirectional from Laboratory Information System (LIS) or middleware to the analyzer.	Same
Test Results	Unidirectional to LIS or middleware from the analyzer.	Same
LAS Communication	GLP systems Track communicates to the analyzer per each analyzer's LAS interface specification.	Same

VIII. Summary of Nonclinical Performance

Nonclinical testing was performed on-site at Abbott to ensure the product met the requirements and aligned with the quality system. This testing included design verification, including both software and hardware verification, as well as design validation. Testing was performed to demonstrate chain of custody of the sample ID. A method comparison study was performed utilizing specimens on the Alinity i Total β-hCG assay. Specimens that were front-loaded (comparator method, Alinity ci multimodule configuration) versus specimens loaded using the GLP systems Track (investigational method, Alinity ci multimodule configuration) were tested and determined to be acceptable. The slope was 0.99 and the correlation coefficient was 1.00 for samples ranging from 4.78 to 14,965.80 mIU/mL using the Total β-hCG assay. The Alinity i Total β-hCG assay is a representative immunoassay available for use with the connected system. However, performance is not limited to use with this assay. Additionally, electromagnetic compatibility (EMC) testing was completed.

IX. Summary of Clinical Performance

This section does not apply.

X. Conclusion Drawn from Nonclinical Laboratory Studies

The submitted information in this premarket notification is complete and supports a substantial equivalence determination.