March 10, 2022

Abbott Laboratories
Michele Smith-Waheed
Associate Director, Regulatory Affairs
100 Abbott Park Rd.
Abbott Park, Illinois 60064

Re: K213486
Trade/Device Name: GLP systems Track
Regulation Number: 21 CFR 862.2160
Regulation Name: Sodium Test System
Regulatory Class: Class II
Product Code: JGS, CEM, CGZ, JJE, JQP
Dated: October 25, 2021
Received: October 29, 2021

Dear Michele Smith-Waheed:

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, Ph.D.
Deputy Director
Division of Chemistry
and Toxicology Devices
OHT7: Office of In Vitro Diagnostics
and Radiological Health
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)*
K213486

Device Name
GLP systems Track

Indications for Use *(Describe)*
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.

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 c ICT (Integrated Chip Technology) is used for the quantitation of sodium, potassium, and chloride in human serum, plasma, or urine on the Alinity c analyzer.

Sodium measurements are used in the diagnosis and treatment of aldosteronism (excessive secretion of the hormone aldosterone), diabetes insipidus (chronic excretion of large amounts of dilute urine, accompanied by extreme thirst), adrenal hypertension, Addison's disease (caused by destruction of the adrenal glands), dehydration, inappropriate antidiuretic hormone secretion, or other diseases involving electrolyte imbalance.

Potassium measurements are used to monitor electrolyte balance in the diagnosis and treatment of diseases conditions characterized by low or high blood potassium levels.

Chloride measurements are used in the diagnosis and treatment of electrolyte and metabolic disorders such as cystic fibrosis and diabetic acidosis.

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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Section 5: 510(k) Summary

This summary of the 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

I. Applicant Name

Abbott Laboratories
100 Abbott Park Rd.
Abbott Park, IL 60064

Primary contact person for all communications:

Michele Smith-Waheed, Associate Director, Regulatory Affairs
Core Diagnostics
Phone: (972) 518-7645

Secondary contact person for all communications:

Amna Shamim, Senior Regulatory Affairs Specialist
Core Diagnostics
Phone: (972) 518-6924

Date Summary Prepared: March 08, 2022

This 510(k) (k213486) is being submitted by Abbott Laboratories for the GLP systems Track developed by Abbott Automation Solutions GmbH (AAS).

II. Device Name

Trade Name: GLP systems Track

Common Name: Laboratory Automation System

Classification Name	Product Code	Class	Regulatory Section	Panel
Discrete photometric chemistry analyzer for clinical use.	JJE	I	21 CFR Sec. - 862.2160	Chemistry (75)
Calculator/data processing module for clinical use.	JQP	I	21 CFR Sec. - 862.2100	Chemistry (75)
Electrode, ion specific, sodium	JGS	II	21 CFR Sec. - 862.1665	Chemistry (75)
Electrode, ion specific, potassium	CEM	II	21 CFR Sec. - 862.1600	Chemistry (75)
Electrode, ion-specific, chloride	CGZ	II	21 CFR Sec. - 862.1170	Chemistry (75)

III. Predicate Device

ACCELERATOR APS (k093318)

IV. Device Description

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.

V. Intended Use of the Device

1. Indication(s) 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.

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 c ICT (Integrated Chip Technology) is used for the quantitation of sodium, potassium, and chloride in human serum, plasma, or urine on the Alinity c analyzer.

Sodium measurements are used in the diagnosis and treatment of aldosteronism (excessive secretion of the hormone aldosterone), diabetes insipidus (chronic excretion of large amounts of dilute urine, accompanied by extreme thirst), adrenal hypertension, Addison's disease (caused by destruction of the adrenal glands), dehydration, inappropriate antidiuretic hormone secretion, or other diseases involving electrolyte imbalance.

Potassium measurements are used to monitor electrolyte balance in the diagnosis and treatment of diseases conditions characterized by low or high blood potassium levels.

Chloride measurements are used in the diagnosis and treatment of electrolyte and metabolic disorders such as cystic fibrosis and diabetic acidosis.

2. Special Condition(s) for Use Statement(s)

Prescription use only.

VI. Comparison of Technological Characteristics

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

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

Characteristics	Subject Device: GLP systems Track (Product Codes JJE, JQP)	Predicate Device: ACCELERATOR APS (k093318) (Product Codes JJE, JQP)	Comparison
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.	The ACCELERATOR APS is a modular system designed to automate sample handling and processing in the clinical laboratory. The system allows consolidation of multiple clinical chemistry and immunoassay analytical instruments into a unified workstation.	Similar (ACCELERATOR APS performs both pre-analytical and post-analytical processing.)
Principle of Analyte Detection	An analyzer's detection method remains the same when interfaced to the GLP systems Track. For example: ARCHITECT/Alinity c systems utilize photometric and potentiometric technology for analyte detection. ARCHITECT/Alinity i systems utilize chemiluminescent labels with magnetic microparticle solid phase for analyte detection.	An analyzer's detection method remains the same when interfaced to the ACCELERATOR APS. For example: ARCHITECT/Alinity c systems utilize photometric and potentiometric technology for analyte detection. ARCHITECT/Alinity i systems utilize chemiluminescent labels with magnetic microparticle solid phase for analyte detection.	Same
Sample Containers	Primary tubes and secondary aliquot tubes.	Primary tubes and secondary aliquot tubes.*	Same
Sample Aspiration	Directly from tube presented to the aspiration point by the GLP systems Track.	Directly from tube presented to the aspiration point by the ACCELERATOR APS.	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.	ACCELERATOR APS IOM accepts samples loaded into sample racks. Samples may also be loaded directly into any analyzers that support local sample loading.	Similar (Functionality is the same, however ACCELERATOR APS does not have a BulkLoader Module).

Characteristics	Subject Device: GLP systems Track (Product Codes JJE, JQP)	Predicate Device: ACCELERATOR APS (k093318) (Product Codes JJE, JQP)	Comparison
Sample Pre-Analytics	Centrifugation: GLP systems Track automatically centrifuges sample tubes. Samples may also be manually centrifuged by lab personnel prior to loading into the system. Decapping: GLP systems Track automatically decaps sample tubes. Samples may also be manually decapped by lab personnel prior to loading into the system. Aliquoting: GLP systems Track automatically aliquots samples from the primary sample to bar coded secondary tubes. Recapping/Resealing: GLP systems Track automatically recaps sample tubes. Samples may also be manually recapped/ resealed by lab personnel prior to loading into 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.	Centrifugation: ACCELERATOR APS automatically centrifuges sample tubes. Samples may also be manually centrifuged by lab personnel prior to loading into system. Decapping: ACCELERATOR APS automatically decaps sample tubes. Samples may also be manually decapped by lab personnel prior to loading into the system. Aliquoting: ACCELERATOR APS automatically aliquots samples from the primary sample to bar coded secondary tubes.* Recapping/Resealing: ACCELERATOR APS automatically reseals sample tubes. Samples may also be manually recapped/resealed by lab personnel prior to loading into the system. Storage: ACCELERATOR APS automatically stores sample tubes in refrigerator storage. Samples may also be returned to IOM for lab personnel to manually store samples in lab.	Same
Sample Transport	GLP systems Track transports sample CARs identified on the system by Near-Field Communication (NFC) tags. Samples may also be manually transported by lab personnel to analyzers.	ACCELERATOR APS transports sample carriers identified on the system by Radio Frequency identification (RFID) tags. Samples may also be manually transported by lab personnel to analyzers.	Similar (NFC tags and RFID tags both identify sample carriers on the system using a wireless method.)
Sample Identification	GLP systems Track reads sample bar codes and electronically communicates sample ID to 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 LAS.	ACCELERATOR APS reads sample bar codes and electronically communicates the sample ID to 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 LAS.	Same
Test Orders	Unidirectional from Laboratory Information System or middleware to the analyzer.	Unidirectional from Laboratory Information System or middleware to the analyzer.	Same

Characteristics	Subject Device: GLP systems Track (Product Codes JJE, JQP)	Predicate Device: ACCELERATOR APS (k093318) (Product Codes JJE, JQP)	Comparison
Test Results	Unidirectional from Laboratory Information System or middleware from the analyzer.	Unidirectional from Laboratory Information System or middleware from the analyzer.	Same
LAS Communication	GLP systems Track communicates to the analyzer per each analyzer's LAS interface specification.	ACCELERATOR APS communicates to the analyzer per each analyzer's LAS interface specification.	Same

*functionality added post-clearance

VII. 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 for Chain of Custody of the sample ID, and a Method Comparison study comparing the use of the GLP systems Track to a manual method was also performed. Additionally, Electromagnetic Compatibility and Electrical Safety testing was completed.

VIII. Summary of Clinical Performance

This section does not apply.

IX. Conclusion Drawn from Nonclinical Laboratory Studies

The results presented in this 510(k) premarket notification for the subject device, GLP systems Track (List No. 04Z96-51), demonstrates substantial equivalence to the predicate device, ACCELERATOR APS (List No. 07L40, k093318).