510(k) SUBSTANTIAL EQUIVALENCE DETERMINATION
DECISION SUMMARY
ASSAY AND INSTRUMENT

I Background Information:

A 510(k) Number

K230937

B Applicant

Abbott Laboratories

C Proprietary and Established Names

GLP systems Track, Alinity i Total β-hCG Reagent Kit

D Regulatory Information

Product Code(s)	Classification	Regulation Section	Panel
DHA	Class II	21 CFR 862.1155 - Human chorionic gonadotropin (HCG) test system	CH - Clinical Chemistry
JJE	Class I	21 CFR 862.2160 - Discrete Photometric Chemistry Analyzer For Clinical Use	CH - Clinical Chemistry
JQP	Class I	21 CFR 862.2100 - Calculator/data processing module for clinical use	CH - Clinical Chemistry

II Submission/Device Overview:

A Purpose for Submission:

The submission is to obtain clearance for the GLP systems Track, a laboratory automation system (LAS) used with clinical chemistry and immunoassay systems such as the Alinity i system and the Alinity ci series.

The manufacturer uses the performance of Total β-hCG assay to compare results obtained from specimens when the same analyzer pipette aspirated either from the instrument front (manual-loaded) or from the instrument back (GLP systems Track loaded).

B Measurand:

Total beta human chorionic gonadotropin (β-hCG)

C Type of Test:

Quantitative and qualitative, chemiluminescent microparticle immunoassay

III Intended Use/Indications for Use:

A Intended Use(s):
See Indications for Use below.

B 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 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.

C Special Conditions for Use Statement(s):
Rx - For Prescription Use Only

D Special Instrument Requirements:

Alinity i system and Alinity ci series

IV Device/System Characteristics:

A 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, decapping of samples, centrifugation, aliquoting of samples, transport of samples between processes (modules), and delivery of samples to one or more Abbott and third Party commercially available laboratory analyzers, capping of samples, and storage of samples. Each module includes a built-in touchscreen, a user interface that functions as a central operating and display element. Due to the modular nature of the LAS, customers may select modules and configurations to fit their laboratory needs.

Alinity i Total β-hCG Reagent Kit
The Alinity i Total β-hCG Reagent Kit consists of magnetic microbeads coated with anti-β-hCG monoclonal antibody in TRIS buffer with protein (bovine) stabilizers and anti-hCG monoclonal antibody labeled with acridinium in MES buffer with protein (bovine) stabilizers. The Reagent Kit is composed of two cartridges, and each cartridge contains two vials (microparticle antibody and conjugate antibody) and a spacer (empty cartridge).

B Principle of Operation:
The Alinity i Total β-hCG assay is a two-step immunoassay for the quantitative and qualitative determination of β-hCG in human serum and plasma using chemiluminescent microparticle immunoassay (CMIA) technology. Sample and anti-β-hCG coated paramagnetic microparticles are combined and incubated. The β-hCG present in the sample binds to the anti-β-hCG coated microparticles. The mixture is washed. Anti-β-hCG 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 relative light units (RLUs). There is a direct relationship between the amount of β-hCG in the sample and the RLUs detected by the system optics.

C Instrument Description Information:

1. Instrument Name:
   GLP systems Track

2. Specimen Identification:
   Barcode identification of patient samples. GLP systems Track reads sample bar codes and electronically communicates sample identification number to the analyzers.

3. Specimen Sampling and Handling:
   The patient's sample tubes are loaded onto the GLP systems Track Input/Output Module (IOM) or BulkLoader Module to be centrifuged, de-capped, aliquoted, recapped and stored. The sample bar codes are read to direct the sample to a specific analyzer.

4. Calibration:
   Provided in k170317 (Alinity i Total ß-hCG Reagent Kit, Alinity i System)

5. Quality Control:
   Provided in k170317 (Alinity i Total ß-hCG Reagent Kit, Alinity i System)

This medical device product has functions subject to FDA premarket review as well as functions that are not subject to FDA premarket review. For this application, if the product has functions that are not subject to FDA premarket review, FDA assessed those functions only to the extent that they either could adversely impact the safety and effectiveness of the functions subject to FDA premarket review or they are included as a labeled positive impact that was considered in the assessment of the functions subject to FDA premarket review.

V Substantial Equivalence Information:

A Predicate Device Name(s):
B Alinity i Total β-hCG Reagent Kit, GLP systems Track

C Predicate 510(k) Number(s):
K170317, K213486

D Comparison with Predicate(s):

Assay Predicate

Device & Predicate Device(s):	K230937	K170317
Device Trade Name	Alinity i Total β-hCG Reagent Kit	Alinity i Total β-hCG Reagent Kit
General Device Characteristic Similarities		
Intended Use/Indications For Use	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.	Same

General Device Characteristic Differences		
Sample Process	Using GLP systems Track	Directly loaded

Instrument Predicate

Device & Predicate Device(s):	K230937	K213486
Device Trade Name	GLP systems Track	GLP systems Track
General Device Characteristic Similarities		
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: GLP systems Track automatically aliquots samples from the primary sample to bar coded secondary tubes.	

Device & Predicate Device(s):	K230937	K213486
Device Trade Name	GLP systems Track	GLP systems Track
General Device Characteristic Similarities		
	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
General Device Characteristic Differences		
Analyzer	Alinity i System; Alinity ci-series	Alinity c System

VI Standards/Guidance Documents Referenced:

CLSI EP09c 3rd Edition-Measurement Procedure Comparison and Bias Estimation Using Patient Samples

EN 61326-1: 2021 Electrical equipment for measurement, control and laboratory use – EMC requirements – Part 1: General requirements

EN 61326-2-6: 2021 Electrical equipment for measurement, control and laboratory use – EMC requirements –Part 2-6: Particular requirements – In vitro diagnostic (IVD) medical equipment

VII Performance Characteristics (if/when applicable):

A Analytical Performance:

1. Precision/Reproducibility:

   Provided in k170317 (Alinity i Total β-hCG Reagent Kit, Alinity i System)

2. Linearity:

   Provided in k170317 (Alinity i Total β-hCG Reagent Kit, Alinity i System)

3. Analytical Specificity/Interference:

   Provided in k170317 (Alinity i Total β-hCG Reagent Kit, Alinity i System)

4. Assay Reportable Range:

   Provided in k170317 (Alinity i Total β-hCG Reagent Kit, Alinity i System)

5. Traceability, Stability, Expected Values (Controls, Calibrators, or Methods):

   Provided in k170317 (Alinity i Total β-hCG Reagent Kit, Alinity i System)

6. Detection Limit:

   Provided in k170317 (Alinity i Total β-hCG Reagent Kit, Alinity i System)

7. Assay Cut-Off:

   Provided in k170317 (Alinity i Total β-hCG Reagent Kit, Alinity i System)

8. Accuracy (Instrument):
   Not applicable

9. Carry-Over:

Provided in k170317 (Alinity i Total β-hCG Reagent Kit, Alinity i System)

B Comparison Studies:

1. Method Comparison with Predicate Device:

A method comparison study was performed based on recommendations in CLSI EP09c. The method comparison study was performed to demonstrate equivalence between results from specimens that were loaded using the GLP systems Track (investigational method) and on the same Alinity ci-series where specimens were loaded in the front (comparator method). A total of 117 native human serum samples spanning the measuring range of the Alinity i Total β-hCG (beta human chorionic gonadotropin) assay were tested. For both methods (i.e., investigational and comparator), samples were tested in singlicate using one lot of reagents, calibrators, and controls on one Alinity ci-series instrument over the course of three non-consecutive days. Only samples with results that were within the measuring interval of the Alinity i Total β-hCG assay were included in the analysis. A Deming regression analysis was performed using all samples by comparing the result from the investigational method versus the result from the comparator method. The regression analysis result is summarized in the table below:

N	Range Tested Candidate (mIU/mL)	Range Tested Comparator (mIU/mL)	Slope	Slope 95% CI	Intercept	Intercept 95% CI	Correlation Coefficient R
117	[4.43, 14965.80]	[4.78, 14828.09]	0.99	[0.99, 1.00]	-0.16	[-1.24, 0.92]	1.00

2. Matrix Comparison:

Provided in k170317 (Alinity i Total β-hCG Reagent Kit, Alinity i System)

C Clinical Studies:

1. Clinical Sensitivity:

Not applicable.

2. Clinical Specificity:

Not applicable.

3. Other Clinical Supportive Data (When 1. and 2. Are Not Applicable):

Not applicable.

D Clinical Cut-Off:

Not applicable.

E Expected Values/Reference Range:

Provided in k170317 (Alinity i Total β-hCG Reagent Kit, Alinity i System)

F Other Supportive Instrument Performance Characteristics Data:

Provided in k170317 (Alinity i Total β-hCG Reagent Kit, Alinity i System)

VIII Proposed Labeling:

The labeling supports the finding of substantial equivalence for this device.

IX Conclusion:

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