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

A. 510(k) Number:
k093318

B. Purpose for Submission:
The submission is to obtain clearance for The ACCELERATOR APS an accessory to clinical laboratory analyzers such as ARCHITECT c8000 analyzer. The submission uses the ARCHITECT c8000 to demonstrate ACCELERATOR barcode sample ID transmission to analyzer and analytical equivalence to manual sample introduction verses automated sample introduction on the analyzer.

C. Measurand:
Sodium, potassium and chloride

D. Type of Test:
Quantitative, ion selective electrode (ISE)

E. Applicant:
Abbott Laboratories

F. Proprietary and Established Names:
ACCELERATOR APS

G. Regulatory Information:

1. Regulation section:

Regulation	Name	Class
21CFR Sec.- 862.1600:	Potassium test system.	2
21CFR Sec.- 862.1170:	Chloride test system.	2
21CFR Sec.- 862.1665:	Sodium test system.	2
21CFR Sec.- 862.2160:	Discrete photometric chemistry analyzer for clinical use.	1
21CFR Sec.- 862.2100:	Calculator/data processing module for clinical use.	1

2. Product code:

Product code	Device Name
CEM	Electrode, ion specific, potassium
CGZ	Electrode, ion-specific, chloride
JGS	Electrode, ion specific, sodium
JJE	Analyzer, chemistry (photometric, discrete), for clinical use
JQP	Calculator/data processing module, for clinical use

4. Panel:
Chemistry (75)

H. Intended Use:

1. Intended use(s):
   See Indication(s) for use below.

2. Indication(s) for use:

   The ACCELERATOR APS (Automated Processing Systems) is a modular system designed to automate pre-analytical processing, sample handling, and processing in the clinical laboratory. The system consolidates multiple analytical instruments into a unified workstation by employing a common sample processing capability.

   The ARCHITECT c8000 System is a discrete photometric chemistry analyzer for clinical use. The device is intended to duplicate manual analytical procedures by performing various steps such as pipetting, heating, and measuring color intensity. This device is intended for use in conjunction with certain materials to measure a variety of analytes that may be adaptable to the analyzer depending on the reagent used. The ARCHITECT c8000 System also has a solid state Ion-Selective Electrode module, utilizing potentiometry, for electrolyte determinations for Sodium, Potassium and Chloride.

   Sodium, Potassium and Chloride measurements are used in the diagnosis and treatment diseases involving electrolyte imbalance.

3. Special conditions for use statement(s):
   Prescription use

4. Special instrument requirements:
   ARCHITECT c8000 System

I. Device Description:

The ACCELERATOR APS (Automated Processing Systems) is a modular system designed to automate pre-analytical sample processing, sample handling, and processing in the clinical laboratory. The system consolidates multiple analytical instruments into a unified workstation by employing a common sample processing capability. The workcell software provides for workload management, sample order management, and instrument operational status monitoring. This is accomplished through communication connections between the workcell, analyzers, and LIS (laboratory information systems) or middleware.

The ACCELERATOR APS performs the following pre and post-analytical functions.

- **Sample bar code identification (previously performed by the analyzer)**
- Sample transport and tracking
- Sample centrifugation (Optional functionality)
- Sample de-capping (Optional functionality)
- Tube sealing (Optional functionality)
- Sample Storage and Retrieval (Optional functionality)

J. Substantial Equivalence Information:

1. Predicate device name(s):
   Abbott, Aeroset with ISE - Integrated Chip Technology (ICT) module (Architect is a family)
   Siemens, Advia Centaur System with StreamLab Analytical Workcell

2. Predicate 510(k) number(s):
   k980367, k082638 respectively

3. Comparison with predicate:
   Similarities and Difference Table to Predicate Device: ARCHITECT c8000

Product Functionality	**Predicate Device:** ARCHITECT c8000 with embedded ICT Module	**Test Device:** ARCHITECT e8000 witb embedded ICT Module and ACCELERATOR APS
Intended Use	The Abbott ARCHITECT System is intended for in vitro diagnostic use only. The Abbott ARCHITECT System is designed to perform automated: Chemistry tests, utilizing photometric and potentiometric technology. Immunoassay tests, utilizing CM1A (Chemiluminescent Micropartic1e assay) detection technology.	Same, with automated pre-analytical sample processing and transporting to the ARCHITECT analyzer.
Principle of Operation	ARCHITECT c Systems utilize photometric and potentiometric technology for analyte detection.	Same
Sample Containers	Primary tubes or sample cups.	Primary Tubes
Sample Aspiration	Directly from Primary tube or sample cup presented to the aspiration point by the ARCHITECT Robotic Sample Handler (RSH).	Directly from Primary tube presented to the aspiration point by the ACCELERATOR APS track or spur.
Sample Handling	Directly loaded into the ARCHITECT via the Robotic Sample Handler (RSH) or Local Sample Handler (LSH). Manually centrifuged sample tubes by laboratory personnel Manually de-capped sample tubes by laboratory personnel Manually re-sealed sample tubes by laboratory personnel External to analyzer: by	Directly loaded into the ARCHITECT via the LSH or via ACCELERATOR APS

Product Functionality	**Predicate Device:** ARCHITECT c8000 with embedded ICT Module	**Test Device:** ARCHITECT e8000 witb embedded ICT Module and ACCELERATOR APS
	laboratory personnel. Internal to analyzer: by Robotic Sample Handler (RSH) or Local Sample Handler (LSH) Bar coded sample tubes read directly by analyzer bar code reader.	
Sample Pre-Antilytics (centrifuge, de-cap, re-seal)		Manually centrifuged sample tubes by laboratory personnel or automatically centrifuged tubes by ACCELERATOR APS
		Manually de-capped sample tubes by laboratory personnel or automatically de-capped tubes by ACCELERATOR APS
		Manually re-sealed sample tubes by laboratory personnel or automatically re-sealed tubes by ACCELERATOR APS
Sample Transportation		External to analyzer: by APS transport carriers identified on the system by RFID tags. Internal: N/A, samples presented to analyzer via ACCELERATOR APS for aspiration.
Sample Identification from bar coded tubes		Bar coded sample tubes read directly by analyzer when placed on LSH, or sample bar code read by ACCELERATOR APS and electronically transferred to the ARCHITECT analyzer when presented at the aspiration point.
Sample Storage Retrieval	Manually stored and retrieved by laboratory personnel	Manually stored and retrieved by laboratory personnel or automatically stored/retrieved by ACCELERATOR APS
Test Orders	Unidirectional from Laboratory Information System (LIS) or middleware to analyzer	Same
Test results	Unidirectional to Laboratory Information System (LIS) or middleware from analyzer	Same

Product Functionality	**Predicate Device:** ARCHITECT c8000 with embedded ICT Module	**Test Device:** ARCHITECT e8000 witb embedded ICT Module and ACCELERATOR APS
LAS Communication	N/A	ARCHITECT software communicates with ACCELERATOR APS via LAS interface.

Similarities and Differences Table to Predicate Device: StreamLAB - k082638

Product Functionality	**Predicate Device: StreamLAB**	**Test Device:** ACCELERATOR APS
Sample Bar Code Identification	**Yes, electronically transferred to the analyzer**	**Same**
Sample Transport and Tracking	Yes	Same
Sample Centrifugation	Yes, Optional Functionality	Same
Sample De-capping	Yes, Optional Functionality	Same
Tube Sealing	Yes, Optional Functionality	Same

K. Standard/Guidance Document Referenced (if applicable):
None were referenced

L. Test Principle:
Ion Selective Electrode (ISE) utilizing potentiometry

M. Performance Characteristics (if/when applicable):

1. Analytical performance:
   a. Precision/Reproducibility:
   Provided in k980367

   b. Linearity/assay reportable range:
   Provided in k980367

   c. Traceability, Stability, Expected values (controls, calibrators, or methods):
   Provided in k980367

   d. Detection limit:
   Provided in k980367

   e. Analytical specificity:
   Provided in k980367

   f. Assay cut-off:
   Not applicable

2. Comparison studies:
   a. *Method comparison with predicate device:*

      The method correlation comparison study was conducted between a stand-alone ARCHITECT c8000 analyzer and an ARCHITECT c8000 analyzer integrated with the ACCELERATOR APS system yielded the following results for the Sodium, Potassium and Chloride assays.

Least Square Analysis

Representative Method	Number of Specimens	Correlation Coefficient	Slope	Y-axis Intercept	Mean % Bias
Sodium	58	0.9941	0.99	1.75	0.03
Potassium	58	0.9999	0.99	0.03	-0.09
Chloride	58	0.9986	0.98	1.32	-0.30

Passing -Bablok Analysis

Representative Method	Number of Specimens	Correlation Coefficient	Slope	Y-axis Intercept	Mean % Bias
Sodium	58	0.9941	0.99	1.75	0.03
Potassium	58	0.9999	0.99	0.02	-0.09
Chloride	58	0.9986	0.98	1.23	-0.30

   b. *Matrix comparison:*
      Not applicable

3. Clinical studies:
   a. *Clinical Sensitivity:*
      Not applicable
   b. *Clinical specificity:*
      Not applicable
   c. Other clinical supportive data (when a. and b. are not applicable):
      Not applicable

4. Clinical cut-off:
   Not applicable

5. Expected values/Reference range:
   Provided in k980367

N. Instrument Name:

ACCELERATOR APS

O. System Descriptions:

1. Modes of Operation:

   The ACCELERATOR APS (Automated Processing Systems) workcell is a modular system designed to automate pre-analytical processing, sample handling, and processing in the clinical laboratory. The system consolidates multiple analytical instruments into a unified workstation by employing a common sample processing capability. The workcell software provides for workload management, sample order management, and instrument operational status monitoring. This is accomplished through communication connections between the workcell, analyzers, and LIS (laboratory information systems) or middleware.

2. Software:

   FDA has reviewed applicant's Hazard Analysis and software development processes for this line of product types:

   Yes ___X_____ or No _____

   The applicant provided software documentation that supports the device was designed and developed under good software LifeCycle processes.

3. Specimen Identification:

   Sample tube bar code (identification) is read by the Architect (when tubes are placed directly on the Architect); or sample tube bar code read by ACCELERATOR APS and communicated electronically to the Architect (when tubes are loaded onto ACCELERATOR APS).

4. Specimen Sampling and Handling:

   The analyzer Interface module provides the path required to move sample tubes to the analyzer. If a sample tube has test requests for an analyzer, the tube carrier is moved to the analyzer for sample aspiration and processing. After sample aspiration, the sample tube is returned to the main lane of the workcell.

5. Calibration:

   Provided in k980367

6. Quality Control:

   Provided in k980367

P. Other Supportive Instrument Performance Characteristics Data Not Covered In

The "Performance Characteristics" Section above:

Various functional test protocols were used to validate the barcode read and transmission capabilities for the ACCELERATOR APS/Architect system. The test protocols were found acceptable.

Q. Proposed Labeling:

The labeling is sufficient and it satisfies the requirements of 21 CFR Part 809.10.

R. Conclusion:

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