K093318

FEB 19 2010

510(k) Summary

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Date of Preparation of this Summary:	February 11, 2010
Device Trade or Proprietary Name:	ACCELERATOR APS
Device Common Name:	APS
Classification Number/Class:	JQP, Class I (APS) JJE, Class I (ARCHITECT) JGS, CEM, CGZ, Class II (Sodium, Potassium, Chloride)

510(k) Summary

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

The assigned 510(k) number is: K093318

Identification of Predicate Device:

Predicate Instrument or Assay	510(k) Number	Product Code
ARCHITECT c8000 System	K980367/A002	JJE
Clinical Chemistry ICT – Sodium, Potassium, Chloride	K980367	JGS,CEM,CGZ
ADVIA Centaur with StreamLAB Analytical Workcell	K082638	JJE

Description:

The following is a brief description of the ACCELERATOR APS System.

ACCELERATOR APS Modules

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)

The ARCHITECT Family of Instruments test instructions and test results for each sample are not processed through the ACCELERATOR APS.

The following analyzers have been validated for use with the ACCELERATOR APS.

- ARCHITECT cSystems (c8000 and c16000)
- ARCHITECT i2000
- ARCHITECT i2000sr

Intended Use:

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.

Substantial Equivalence:

The substantial equivalence will be demonstrated through a Method Comparison study between a standalone ARCHITECT c8000 analyzer and an ARCHITECT c8000 analyzer

integrated to the ACCELERATOR APS system, utilizing the same specimens uniquely labeled with individual sample tube barcode labels for sample identification (SID).

The substantial equivalence testing was conducted utilizing the ARCHITECT c8000 ICT Module for the electrolytes of Sodium, Potassium and Chloride.

Similarities and Difference Table to Predicate Device: *ARCHITECT c8000*

Product Functionality	**Predicate Device: ARCHITECT c8000 with embedded ICT Module**	**Test Device: ARCHITECT c8000 with embedded ICT Module and ACCLERATOR 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 CMIA (*Chemiluminescent* Microparticle 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. ARCHITECT I System utilizes Chemiluminescent labels with magnetic-microparticle solid phase, for analyte detection.	Same
Sample Containers	Primary tubes or sample cups.	Primary Tubes

Product Functionality	Predicate Device: ARCHITECT c8000 with embedded ICT Module	Test Device: ARCHITECT c8000 with embedded ICT Module and ACCLERATOR APS
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).	Directly loaded into the ARCHITECT via the LSH for i2000, c8000, c16000 or via ACCELERATOR APS
Sample Pre-Analytics (centrifuge, de-cap, re-seal)	Manually centrifuged sample tubes by laboratory personnel	Manually centrifuged sample tubes by laboratory personnel or automatically centrifuged tubes by ACCELERATOR APS
	Manually de-capped sample tubes by laboratory personnel	Manually de-capped sample tubes by laboratory personnel or automatically de-capped tubes by ACCELERATOR APS
	Manually re-sealed sample tubes by laboratory personnel	Manually re-sealed sample tubes by laboratory personnel or automatically re-sealed tubes by ACCELERATOR APS
Sample Transportation	External to analyzer: by laboratory personnel. Internal to analyzer: by Robotic Sample Handler (RSH) or Local Sample Handler (LSH)	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.

Product Functionality	Predicate Device: ARCHITECT c8000 with embedded ICT Module	Test Device: ARCHITECT c8000 with embedded ICT Module and ACCELERATOR APS
Sample Identification from bar coded tubes	Bar coded sample tubes read directly by analyzer bar code reader.	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
LAS Communication	N/A	ARCHITECT software communicates with ACCELERATOR APS via LAS interface.

Similarities and Difference Table to Predicate Device: StreamLAB

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
Sample Storage (optional)	Not Available	Sample Storage and Retrieval Module, Optional Functionality

Performance Characteristics:

The method correlation comparison study was conducted between a standalone 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

Acceptance Criteria

Representative Method	Minimum Number of Specimens	Correlation Coefficient	Slope	Mean % Bias
Sodium	57	$\geq$0.975	0.95-1.05	$\leq$3%@ 120-150 mmol/L
Potassium	57	$\geq$0.975	0.95-1.05	$\leq$3%@ 3.0-6.0 mmol/L
Chloride	58	$\geq$0.975	0.95-1.05	$\leq$3%@ 90-120 mmol/L

Conclusion:

The data demonstrates that the performance between a standalone ARCHITECT c8000 and an ARCHITECT c8000 integrated to an ACCELERATOR APS are substantially equivalent.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
10903 New Hampshire Avenue
Document Mail Center – WO66-0609
Silver Spring, MD 20993-0002

FEB 19 2010

Abbott Laboratories
c/o Mark Littlefield
Regulatory Affairs, Manager
1920 Hurd Drive, LC-2, MS 1-8
Irving, TX 75038

Re: k093318
Trade/Device Name: ACCELERATOR APS
Regulation Number: 21 CFR Sec. - 862.1600
Regulation Name: Potassium test system.
Regulatory Class: II
Product Code: CEM, CGZ, JGS, JJE, JQP
Dated: January 5, 2010
Received: January 6, 2010

Dear: Mr. Littlefield:

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. 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.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. 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 Parts 801 and 809); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820).

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of *In Vitro* Diagnostic Device Evaluation and Safety at (301) 796-5450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (301) 796-5760. For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-5680 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Courtney C. Harper, Ph.D.
Director
Division of Chemistry and Toxicology
Office of *In Vitro* Diagnostic Device
Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

Indication for Use

510(k) Number (if known): k093318

Device Name: ACCELERATOR APS

Indication 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.

Prescription Use __X__ And/Or Over the Counter Use ____.
(21 CFR Part 801 Subpart D) (21 CFR Part 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE; CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Device Evaluation and Safety (OIVD)

Carol C Benson

Division Sign-Off
Office of In Vitro Diagnostic Device
Evaluation and Safety

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