510 k Summary k121012

Submitter's name/address	Inpeco S.p.A. Via Giuseppe di Vittorio 11 20090 Segrate, Milan, Italy
Primary Contact Person	Roberto Tamborra Regulatory Affairs Manager roberto.tamborra@inpeco.com Phone number: +39 02 36681263 Mobile Phone number +39 334 6669384
Secondary Contact Person	Luisa Mella Regulatory Affairs Specialist luisa.mella@inpeco.com Phone number: +39 02 36681316
Date of preparation of this Summary:	2012-03-30
Device Trade or Proprietary Name:	FlexLab 3.6 ACCELERATOR a3600
Device Common Name:	Laboratory Automation
Classification Number/Class:	JQP, Class I (FlexLab 3.6 and ACCELERATOR a3600) JJE, Class I (ARCHITECT) JGS, CEM, CGZ, Class II (Sodium, Potassium, Chloride)

AUG 31 2012

Please consider that FlexLab 3.6 and ACCELERATOR a3600 are exactly the same product, the only difference is in the brand name.

In the annexes sometimes only FlexLab 3.6 brand name is listed but all the documents are valid also for ACCELERATOR a3600 brand name. This happens because internally the project was developed under FlexLab 3.6 brand name and then the product will be sold with two different brand names: FlexLab 3.6 and ACCELERATOR a3600.

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: ___k121012__

Identification of Predicate Device:

Predicate Instrument or Assay	510(k) Number	Product Code
APS Accelerator	K093318	JQP

Description:

The following is a brief description of the FlexLab 3.6 system.

The FlexLab 3.6 Automation is a modular system designed to automate Pre-Analytical and Post-Analytical processing, sample handling in order to automate sample processing in the Laboratory.
The system consolidates multiple Analytical instruments into a unified workstation.

The Automation software provides for workload management, sample routing to relevant Analytical instrument based on sample orders coming from LIS (Laboratory Information System) and instrument operational status monitoring. This is accomplished through communication connections between the Automation, Analytical instruments and LIS (Laboratory Information System) or middleware.

Pre-Analytical and Post-Analytical processing in details are as follows: sample loading and unloading and sample identification, sample transport along the system and routing to relevant modules, loading and unloading in centrifuge, decapping, sealing, desealing, storing in a temperature controlled environment, aliquoting, aliquot samples capping, sample presentation to connected Analytical instruments.

The FlexLab 3.6 Automation Systems perform 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)
Sample re-capping (Optional functionality)
Sample sealing (Optional functionality)
Sample de-sealing (Optional functionality)
Sample aliquoting (Optional functionality)
Sample Storage and Retrieval (Optional functionality)

Intended Use:

The FlexLab 3.6 Automation is a modular system designed to automate Pre-Analytical and Post-Analytical processing, sample handling in order to automate sample processing in the Laboratory.

The system consolidates analytical instruments, such as the ARCHITECT c8000 System into a unified workstation that performs a variety of instrument specific assays such as Sodium, Potassium and Chloride.

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

Substantial Equivalence:

The substantial equivalence is demonstrated through a Method Comparison Study between an ARCHITECT c8000 analyzer integrated to the FlexLab 3.6system, and an ARCHITECT c8000 analyzer integrated to an ACCELERATOR APS utilizing the same specimens uniquely labeled with individual sample tube barcode labels for sample identification (SID).

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

The FlexLab 3.6, as an accessory to the analyzers, does not change, expand, or limit the intended use of each analyzer product.

Table 5-1: Similarities and Difference Table to Predicate Devices

Product Functionality	**Predicate Device: ARCHITECT c8000 with embedded ICT Module integrated to ACCELERATOR APS**	**Test Device: ARCHITECT c8000 with embedded ICT Module integrated to FlexLab 3.6**
Intended Use	Same, with automated pre-analytical sample processing and transporting to the ARCHITECT analyzer	Same, with automated pre-analytical sample processing and transporting to the ARCHITECT analyzer
Principle of Operation	Same	Same
Sample Containers	Primary or Aliquot Tubes	Primary and secondary Tubes
Sample Aspiration	Directly from primary tube presented to the aspiration point by the ACCELERATOR APS track or spur	Directly from primary tube presented to the aspiration point by the FlexLab 3.6 track or spur
Sample Handling	Directly loaded into the ARCHITECT via the LSH or via ACCELERATOR APS	Directly loaded into the ARCHITECT via the LSH or via FlexLab 3.6
Sample Pre-Analytics (centrifuge, de-cap, re-seal, re-cap, aliquoter)	Manually centrifuged sample tubes by laboratory personnel or automatically centrifuged tubes by ACCELERATOR APS	Manually centrifuged sample tubes by laboratory personnel or automatically centrifuged tubes by FlexLab 3.6
	Manually de-capped sample tubes by laboratory personnel or automatically de-capped tubes by ACCELERATOR APS	Manually de-capped sample tubes by laboratory personnel or automatically de-capped tubes by FlexLab 3.6
	Manually re-sealed sample tubes by laboratory personnel or automatically re-sealed tubes by ACCELERATOR APS	Manually re-sealed sample tubes by laboratory personnel or automatically re-sealed tubes by FlexLab 3.6
	Manually aliquoted samples by laboratory personnel or automatically aliquoted tubes by ACCELERATOR APS	Manually aliquoted samples by laboratory personnel or automatically aliquoted tubes by
	Same	Same

Sample Transportation	External to analyzer: by ACCELERATOR APS transport carriers identified on the system by RFID tags. Internal to analyzer: N/A, samples presented to analyzer via ACCELERATOR a3600 for aspiration.	External to analyzer: by FlexLab 3.6 transport carriers identified on the system by RFID tags. Internal to analyzer: N/A, samples presented to analyzer via FlexLab 3.6 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 c8000 analyzer when presented at the aspiration point	Bar coded sample tubes read directly by analyzer when placed on LSH, or sample bar code read by FlexLab 3.6 and electronically transferred to the ARCHITECT c8000 analyzer when presented at the aspiration point
Sample Storage/Retrieval	Manually stored and retrieved by laboratory personnel or automatically stored/retrieved by ACCELERATOR APS	Manually stored and retrieved by laboratory personnel or automatically stored/retrieved by FlexLab 3.6
Test Orders	Same	Same
Test Results	Same	Same
LAS Communication	ARCHITECT software communicates with ACCELERATOR APS via LAS interface	ARCHITECT software communicates with FlexLab 3.6 via LAS interface
LIS Communication	ARCHITECT software communicates with hospital LIS via ACCELERATOR APS data management system interface	ARCHITECT software communicates with hospital LIS via FlexLab 3.6 data management system interface

Performance Characteristics:

The method correlation comparison study was conducted between:

- an ARCHITECT c8000 analyzer integrated with the FlexLab 3.6 system and an ARCHITECT c8000 analyzer integrated with the ACCELERATOR APS system

and yielded the following results for the Sodium, Potassium and Chloride assays:

Chloride

Method Comparison Data FlexLab 3.6 vs. ACCELERATOR APS
1st Replicate versus Mean - Chloride Assay - Linear Range

CI		Least Squares				Deming				Passing-Bablok				Bias / Total Error			
		Slope		Intercept		Slope		Intercept		Slope		Intercept					
N	Corr Coef	Slope	%95 CI	Int	95% CI	Slope	%95 CI	Int	95% CI	Slope	95% CI	Int	95% CI	Mean Bias	Mean % Bias	SD of Mean % Bias	Absolute Value of % Total Error
100	0.9993	1.00	(0.99, 1.01)	-0.90	(-1.70, -0.09)	1.00	(0.99, 1.01)	-0.97	(-1.65, -0.29)	1.00	(0.99, 1.01)	-0.89	(-1.61, -0.23)	-0.81	-0.8	0.72	2.3

Method Comparison Data FlexLab 3.6 vs. ACCELERATOR APS
Mean versus Mean Chloride Assay - Linear Range

CI		Least Squares				Deming				Passing-Bablok				Bias / Total Error			
		Slope		Intercept		Slope		Intercept		Slope		Intercept					
N	Corr Coef	Slope	%95 CI	Int	95% CI	Slope	%95 CI	Int	95% CI	Slope	95% CI	Int	95% CI	Mean Bias	Mean % Bias	SD of Mean % Bias	Absolute Value of % Total Error
100	0.9997	1.00	(1.00, 1.01)	-1.13	(-1.68, -0.58)	1.00	(1.00, 1.01)	-1.17	(-1.74, -0.59)	1.00	(0.99, 1.01)	-0.91	(-1.40, -0.28)	-0.85	-0.9	0.56	2.0

Potassium

Method Comparison Data FlexLab 3.6 vs. ACCELERATOR APS
1st Replicate versus Mean Potassium Assay - Linear Range

K		Least Squares				Deming				Passing-Bablok				Bias / Total Error			
		Slope		Intercept		Slope		Intercept		Slope		Intercept					
N	Corr Coef	Slope	%95 CI	Int	95% CI	Slope	%95 CI	Int	95% CI	Slope	95% CI	Int	95% CI	Mean Bias	Mean % Bias	SD of Mean % Bias	Absolute Value of % Total Error
100	0.9995	1.00	(1.00, 1.01)	-0.06	(-0.09, -0.03)	1.00	(1.00, 1.01)	-0.06	(-0.09, -0.03)	1.00	(1.00, 1.01)	-0.05	(-0.07, -0.02)	-0.03	-0.8	1.11	3.0

Method Comparison Data FlexLab 3.6 vs. ACCELERATOR APS
Mean versus Mean Potassium Assay - Linear Range

K		Least Squares				Deming				Passing-Bablok				Bias / Total Error			
		Slope		Intercept		Slope		Intercept		Slope		Intercept					
N	Corr Coef	Slope	%95 CI	Int	95% CI	Slope	%95 CI	Int	95% CI	Slope	95% CI	Int	95% CI	Mean Bias	Mean % Bias	SD of Mean % Bias	Absolute Value of % Total Error
100	0.9997	1.00	(1.00, 1.01)	-0.06	(-0.08, -0.03)	1.00	(1.00, 1.01)	-0.06	(-0.08, -0.03)	1.00	(1.00, 1.01)	-0.04	(-0.06, -0.02)	-0.04	-0.9	0.97	2.8

Sodium

Method Comparison Data FlexLab 3.6 vs. ACCELERATOR APS
1st Replicate versus Mean Sodium Assay - Linear Range

Na		Least Squares				Deming				Passing-Bablok				Bias / Total Error			
		Slope		Intercept		Slope		Intercept		Slope		Intercept					
N	Corr Coef	Slope	%95 CI	Int	95% CI	Slope	%95 CI	Int	95% CI	Slope	95% CI	Int	95% CI	Mean Bias	Mean % Bias	SD of Mean % Bias	Absolute Value of % Total Error
100	0.9993	1.01	(1.00, 1.02)	-2.37	(-3.50, -1.25)	1.01	(1.00, 1.02)	-2.48	(-3.63, -1.33)	1.02	(1.01, 1.03)	-3.08	(-4.72, -1.97)	-0.76	-0.6	0.90	2.4

Method Comparison Data FlexLab 3.6 vs. ACCELERATOR APS
Mean versus Mean Sodium Assay - Linear Range

Na		Least Squares				Deming				Passing-Bablok				Bias / Total Error			
		Slope		Intercept		Slope		Intercept		Slope		Intercept					
N	Corr Coef	Slope	%95 CI	Int	95% CI	Slope	%95 CI	Int	95% CI	Slope	95% CI	Int	95% CI	Mean Bias	Mean % Bias	SD of Mean % Bias	Absolute Value of % Total Error
100	0.9997	1.01	(1.01, 1.02)	-2.46	(-3.20, -1.72)	1.01	(1.00, 1.02)	-2.51	(-3.42, -1.59)	1.01	(1.01, 1.02)	-2.61	(-3.82, -1.74)	-0.87	-0.7	0.74	2.2

Conclusion:

The data demonstrate that the performance of an ARCHITECT c8000 integrated with a FlexLab 3.6 LAS and an ARCHITECT c8000 integrated with an ACCELERATOR APS LAS are substantial equivalent.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration

10903 New Hampshire Avenue
Silver Spring, MD 20993

Inpeco, S.p.a.
c/o Roberto Tamborra
11Via Giuseppe Di Vittorio
Segrate, Milan, 20090
Italy

AUG 31 2012

Re: k121012
Trade Name: FlexLab 3.6
Regulation Number: 21 CFR §862.1600
Regulation Name: Potassium test system
Regulatory Class: Class II
Product Codes: CEM, CGZ, JGS, JJE, JQP
Dated: August 31, 2012
Received: August 31, 2012

Dear Mr. Tamborra:

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

Enclosure

Indications for use statement

510(k) Number (if known): k121012

Device Name: FlexLab 3.6

Indications for Use:

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

Prescription Use ___X___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

Yung Chan

Division Sign-Off
Office of In Vitro Diagnostic Device
Evaluation and Safety
510(k) K121012