A. 510(k) Number:

k121012

B. Purpose for Submission:

The submission is to obtain clearance for FlexLab 3.6 as an accessory to clinical laboratory analyzers such as ARCHITECT c8000 analyzer. The manufacturer uses the ARCHITECT c8000 to demonstrate FlexLab 3.6 barcode sample ID transmission to the analyzer and analytical equivalence to manual sample introduction versus automated sample introduction on the analyzer.

C. Manufacturer and Instrument Name:

Inpeco, FlexLab 3.6 (distributed as: Abbott Laboratories ACCELERATOR a3600)

D. Type of Test or Tests Performed:

Quantitative, ion selective electrode (ISE)

E. System Descriptions:

1. Device Description:

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 that communicates with Hospital information System (HIS).

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 or middleware.

Pre-analytical and post-analytical processing are as follows: sample loading and unloading and sample identification by barcode read (previously done by the analyzer), sample transport along the system and routing to relevant modules, loading and unloading in centrifuge, de-capping, sealing, de-sealing, storing in a
temperature controlled environment, aliquoting, aliquot sample capping, and sample presentation to connected analytical instruments.

2. **Principles of Operation:**

   Ion selective electrode (ISE) using potentiometry

3. **Modes of Operation:**

   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 or middleware.

4. **Specimen Identification:**

   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

5. **Specimen Sampling and Handling:**

   The analyzer interface module provides the path required to move sample tubes to the analyzer and directly loaded into the ARCHITECT via the LSH or via FlexLab 3.6 Sampling takes place directly from the primary tube presented to the aspiration point by the FlexLab 3.6 track or spur.

6. **Calibration:**

   - Provided in k093318

7. **Quality Control:**

   - Provided in k093318

8. **Software:**

   FDA has reviewed applicant’s Hazard Analysis and Software Development processes for this line of product types:
Yes____X____ or No________

F. Regulatory Information:

<table>
<thead>
<tr>
<th>Product Code</th>
<th>Classification</th>
<th>Regulation Section</th>
<th>Panel</th>
</tr>
</thead>
<tbody>
<tr>
<td>JJE – Analyzer, chemistry (photometric, discrete), for clinical use</td>
<td>Class I</td>
<td>21 CFR § 862.2160</td>
<td>Clinical Chemistry (75)</td>
</tr>
<tr>
<td>JQP – Calculator/data processing module, for clinical use</td>
<td>Class I</td>
<td>21 CFR § 862.2100</td>
<td>Clinical Chemistry (75)</td>
</tr>
<tr>
<td>CEM – Potassium test system</td>
<td>Class II</td>
<td>21 CFR § 862.1600</td>
<td>Clinical Chemistry (75)</td>
</tr>
<tr>
<td>CGZ – Chloride test system</td>
<td>Class II</td>
<td>21 CFR § 862.1170</td>
<td>Clinical Chemistry (75)</td>
</tr>
<tr>
<td>JGS – Sodium test system</td>
<td>Class II</td>
<td>21 CFR § 862.1665</td>
<td>Clinical Chemistry (75)</td>
</tr>
</tbody>
</table>

G. Intended Use:

1. Indication(s) for 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.

2. Special Conditions for Use Statement(s):

   Prescription use only

H. Substantial Equivalence Information:

1. Predicate Device Name(s) and 510(k) numbers:
### Comparison with Predicate Device:

<table>
<thead>
<tr>
<th>Item</th>
<th>Device</th>
<th>Predicate: ARCHITECT c8000 with embedded ICT Module integrated to ACCELERATOR APS</th>
</tr>
</thead>
<tbody>
<tr>
<td>Intended Use</td>
<td>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.</td>
<td>Same</td>
</tr>
<tr>
<td>Principle of Operation</td>
<td>ARCHITECT c8000 Systems utilize photometric and potentiometric technology for analyte detection</td>
<td>Same</td>
</tr>
<tr>
<td>Sample Containers</td>
<td>Primary and secondary tubes</td>
<td>Same</td>
</tr>
<tr>
<td>Sample Handling</td>
<td>Directly loaded into the ARCHITECT via the LSH or via FlexLab 3.6</td>
<td>Same</td>
</tr>
<tr>
<td>Sample Pre-Analytics</td>
<td>Sample tubes are centrifuged, de-capped, re-sealed, and aliquoted manually by laboratory personnel or automatically by FlexLab 3.6</td>
<td>Same</td>
</tr>
<tr>
<td></td>
<td>Sample Pre-Analytics (re-cap)</td>
<td>Same</td>
</tr>
<tr>
<td>Item</td>
<td>Device</td>
<td>Predicate: ARCHITECT c8000 with embedded ICT Module integrated to ACCELERATOR APS</td>
</tr>
<tr>
<td>------------------------------------------</td>
<td>------------------------------------------------------------------------</td>
<td>--------------------------------------------------------------------------------</td>
</tr>
<tr>
<td>Sample Transportation</td>
<td>External to analyzer: by FlexLab 3.6 transport carriers identified on the system by RFID tags</td>
<td>External to analyzer: Same</td>
</tr>
<tr>
<td></td>
<td>Internal to analyzer: N/A, sample presented to analyzer via FlexLab 3.6 for aspiration.</td>
<td>Internal to analyzer: Same</td>
</tr>
<tr>
<td>Sample Identification from bar coded tubes</td>
<td>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</td>
<td>Same</td>
</tr>
<tr>
<td>Sample Storage/Retrieval</td>
<td>Manually stored and retrieved by laboratory personnel or automatically stored/retrieved by FlexLab 3.6</td>
<td>Same</td>
</tr>
<tr>
<td>Test Orders</td>
<td>Unidirectional from Laboratory Information System (LIS) or middleware to analyzer</td>
<td>Same</td>
</tr>
<tr>
<td>Test Results</td>
<td>Unidirectional from Laboratory Information System (LIS) or middleware to analyzer</td>
<td>Same</td>
</tr>
<tr>
<td>LAS Communication</td>
<td>ARCHITECT software communicates with FlexLab 3.6 via LAS interface</td>
<td>Same</td>
</tr>
<tr>
<td>LIS Communication</td>
<td>ARCHITECT software communicates with hospital LIS via FlexLab 3.6 data management system interface</td>
<td>Same</td>
</tr>
</tbody>
</table>

I. Special Control/Guidance Document Referenced (if applicable):

Safety requirements for electrical equipment for measurement, control, and laboratory use. UL61010-1:2001 (2nd edition)
J. Performance Characteristics:

1. Analytical Performance:
   
a. Accuracy:
      - Provided in k093318

b. Precision/Reproducibility:
   - Provided in k093318

c. Linearity:
   - Provided in k093318

d. Carryover:
   - Not applicable

e. Interfering Substances:
   - Not applicable

2. Other Supportive Instrument Performance Data Not Covered Above:

   Comparison studies:

   a. Method comparison with predicate device:

      The method correlation comparison study was conducted between an ARCHITECT c8000 analyzer with FlexLab 3.6 and an ARCHITECT c8000 analyzer with ACCERLERATOR APS yielded the following results for the Sodium, Potassium and Chloride assays.

**Chloride:**

<table>
<thead>
<tr>
<th>Regression Method</th>
<th>Number of Specimens</th>
<th>Correlation Coefficient</th>
<th>Slope (95% CI)</th>
<th>Y-axis Intercept (95% CI)</th>
<th>Mean % Bias</th>
</tr>
</thead>
<tbody>
<tr>
<td>Least Squares</td>
<td>100</td>
<td>0.9993</td>
<td>1.00 (0.99, 1.01)</td>
<td>-0.90 (-1.70, -0.09)</td>
<td>-0.8</td>
</tr>
<tr>
<td>Deming</td>
<td>100</td>
<td>0.9993</td>
<td>1.00 (0.99, 1.01)</td>
<td>-0.97 (-1.65, -0.29)</td>
<td></td>
</tr>
<tr>
<td>Passing-Bablok</td>
<td>100</td>
<td>0.9993</td>
<td>1.00 (0.99, 1.01)</td>
<td>-0.89 (-1.61, -0.23)</td>
<td></td>
</tr>
</tbody>
</table>
### Potassium:

<table>
<thead>
<tr>
<th>Regression Method</th>
<th>Number of Specimens</th>
<th>Correlation Coefficient</th>
<th>Slope (95% CI)</th>
<th>Y-axis Intercept (95% CI)</th>
<th>Mean % Bias</th>
</tr>
</thead>
<tbody>
<tr>
<td>Least Squares</td>
<td>100</td>
<td>0.9995</td>
<td>1.00 (1.00, 1.01)</td>
<td>-0.06 (-0.09, -0.03)</td>
<td>-0.8</td>
</tr>
<tr>
<td>Deming</td>
<td>100</td>
<td>0.9995</td>
<td>1.00 (1.00, 1.01)</td>
<td>-0.06 (-0.09, -0.03)</td>
<td></td>
</tr>
<tr>
<td>Passing-Bablok</td>
<td>100</td>
<td>0.9995</td>
<td>1.00 (1.00, 1.01)</td>
<td>-0.05 (-0.07, -0.02)</td>
<td></td>
</tr>
</tbody>
</table>

### Sodium:

<table>
<thead>
<tr>
<th>Regression Method</th>
<th>Number of Specimens</th>
<th>Correlation Coefficient</th>
<th>Slope (95% CI)</th>
<th>Y-axis Intercept (95% CI)</th>
<th>Mean % Bias</th>
</tr>
</thead>
<tbody>
<tr>
<td>Least Squares</td>
<td>100</td>
<td>0.9993</td>
<td>1.01 (1.00, 1.02)</td>
<td>-2.37 (-3.50, -1.25)</td>
<td>-0.6</td>
</tr>
<tr>
<td>Deming</td>
<td>100</td>
<td>0.9993</td>
<td>1.01 (1.00, 1.02)</td>
<td>-2.48 (-3.63, -1.33)</td>
<td></td>
</tr>
<tr>
<td>Passing-Bablok</td>
<td>100</td>
<td>0.9993</td>
<td>1.02 (1.01, 1.03)</td>
<td>3.08 (-4.72, -1.97)</td>
<td></td>
</tr>
</tbody>
</table>

b. Software/Hardware Verification and Validation:

Various functional test protocols were used to validate the barcode read and transmission capabilities for the FlexLab 3.6/Architect c8000 system. The test protocols were found to be acceptable.

K. Proposed Labeling:

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

L. Conclusion:

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