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

A. 510(k) Number:
k090588

B. Purpose for Submission:
This is a new 510(k) to support the integration of a Power Processor Sample Processing System to the UniCel DxI 600/800 Access Immunoassay System (k023764) using cleared Vitamin B12, Ferritin, Folate and TSH Access Immunoassays to show acceptable performance.

C. Measurand:
Vitamin B12, Ferritin, Folate and TSH

D. Type of Test:
Quantitative Chemiluminescent Immunoassay

E. Applicant:
Beckman Coulter, Inc.

F. Proprietary and Established Names:
Power Processor Sample Processing System with Generic Connection Module, Model: 4210

G. Regulatory Information:

1. Regulation section:
   21CFR Sec.-862.1810 - Vitamin B12 test system.
   21CFR Sec.-866.5340 - Ferritin immunological test system.
   21CFR Sec.-862.1295 - Folic acid test system.
   21CFR Sec.-862.1690 - Thyroid stimulating hormone test system.
   21CFR Sec.- 862.2160 - Discrete photometric chemistry analyzer for clinical use.

2. Classification:
   II, II, II, II, I respectively

3. Product code:
   CDD - Radioassay, Vitamin B12
   DBF - Ferritin, Antigen, Antiserum, Control
   CGN - Acid, Folic, Radioimmunoassay
   JLW - Radioimmunoassay, Thyroid-Stimulating Hormone
   JJE - Analyzer, Chemistry (Photometric, Discrete), For Clinical Use

4. Panel:
   Chemistry (75) Immunology (91)

H. Intended Use:

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

2. Indication(s) for use:
   The basic Power Processor is an automated sample handling system which processes sample tubes from the pre-centrifugation, pre-sorting step to presentation of centrifuged and decapped samples into Generic or Personality Racks for specific instruments. The Power Processor can be configured with optional software and hardware to allow processing of sample tubes on Generic Connection Instruments. The Power Processor performs all pre-analytical sample tube preparation, and then sorts the sample tubes directly to Generic Connection Modules where the samples are pipetted by the Generic Connection instrument for testing. After the samples are pipetted, the tubes can route to other instruments for additional testing or to Outlet Racks.

   The UniCel DxI 800 Access Immunoassay System with laboratory automation connection is a microcomputer-controlled, random and continuous access analyzer that includes an external computer. This computer stores the system user interface (UI) software and allows the operator to interface with and direct the instrument software. The UniCel DxI 800 System uses enzyme immunoassays (utilizing paramagnetic particle solid phase and chemiluminescent detection) for determination of various analytes, such as Vitamin B12, Ferritin, Folate and hTSH along with other various enzyme immunoassays assays that may be adaptable to the analyzer depending on the reagent used to induce the enzyme immunoassay reaction. The UniCel DxI 800 System is an in vitro diagnostic device for use in the clinical laboratory.

   The Access Ferritin assay is a paramagnetic particle, chemiluminescent assay for the quantitative determination of ferritin levels in human serum and plasma (heparin) using the Access Immunoassay Systems. Measurements of ferritin aid in the diagnosis of diseases affecting iron metabolism.

   The Access Folate assay is a paramagnetic particle, chemiluminescent immunoassay for the quantitative determination of folic acid levels in human serum, plasma (heparin) and red blood cells using the Access Immunoassay Systems. Folic acid measurements are used in the diagnosis and treatment of megaloblastic anemia.

   The Access HYPER sensitive hTSH assay is a paramagnetic particle, chemiluminescent assay for the quantitative determination of human thyroid-stimulating hormone (thyrotropin, hTSH) levels in human serum using the Access Immunoassay Systems. Measurements of thyroid stimulating hormone produced by the anterior pituitary are used in the diagnosis of thyroid or pituitary disorders.

The Access Vitamin B12 assay is a paramagnetic particle, chemiluminescent assay for the quantitative determination of vitamin B12 in human serum and plasma (heparin) using Access Immunoassay Systems. Measurements obtained by this device are used in the diagnosis and treatment of anemias of gastrointestinal malabsorption.

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

4. Special instrument requirements:
   UniCel DxI 800 Access Immunoassay System

I. Device Description:

The Power Processor is a scalable laboratory automation system (LAS) designed to streamline pre-analytical processes in the clinical laboratory. A basic Power Processor System is comprised of a Line Control Computer, Preplink™ Computer, Inlet Module, Hematology Module, Centrifugation Module, Decapper Module, and Outlet Module. In the basic configuration, patient sample tubes are loaded onto the Power Processor system to be sorted to a Hematology Module, or to be centrifuged, decapped, and sorted to Personality Racks for further processing on other instruments. Additional modules may be added for aliquot capability, sample capping, and refrigerated storage.

The Power Processor is an open architecture system that can connect to a variety of clinical analyzers. Connection modules are extensions of the Power Processor track system that link with an analyzer's existing LAS interface. Connection modules support one of two types of sample transfer methods: onboard or outboard sampling. Onboard sampling physically transfers the sample tube/rack from the automation track to the analyzer's sample load and identification area. With outboard sampling, the connection unit performs the sample bar code read function, presents the sample ID to the connected analyzer, and then signals for direct sampling of the open tube by the connected instrument at an aspiration point on the automation track. The Power Processor Generic Connection Module is specifically designed to support the outboard sampling method based on point-in space pipetting technology aligned with the CSLI guidelines. This method is used to establish connection with Beckman Coulter's UniCel DxI 800 Immunoassay System. Power Processor software version 3.5 establishes a dynamic or "smart" connection with the UniCel DxI 800 System to enable sample routing based on reagent and calibration status.

J. Substantial Equivalence Information:

1. Predicate device name(s):

Predicate Device	510(k) Number
Siemens (Dade Behring) StreamLAB® Analytical WorkCell/Sample Transfer Module	k043546

Beckman Coulter UniCel® DxI 800 Access® Immunoassay System	k023764
Beckman Coulter Access® Ferritin Assay	k926221
Beckman Coulter Access® Folate Assay	k060774
Beckman Coulter Access® HYPERsensitive hTSH Assay	k042281
Beckman Coulter Access® Vitamin B12 Assay	k955436

2. Predicate 510(k) number(s):
   See Predicate Device table above.

3. Comparison with predicate:

Aspect/ Characteristic	Device	Predicate
Intended Use	The basic Power Processor is an automated sample handling system which processes sample tubes from the pre-centrifugation, pre-sorting step to presentation of centrifuged and decapped samples into Generic or Personality Racks for specific instruments. The system is designed to free laboratory personnel from biohazard exposure and routine sample preparation. The Power Processor can be configured with optional software and hardware to allow processing of sample tubes . The Power Processor performs all preanalytical sample tube preparation, then sorts the sample tubes directly to Generic Connection Modules where the samples are pipetted for testing. After the samples are pipetted, the tubes can route to other instruments for additional testing or to Outlet Racks.	Same: Automated sample handling, routing, and management system designed to increase productivity and improve operator safety.
System Design	Open LAS architecture enables multiple analyzer connections. Scalable, modular configuration.	Same
Sample Transfer Method	Outboard sampling capability using the analyzer's existing LAS interface and Generic Connection Module.	Same, using STM device.
Fundamental Technology	Outboard analyzer connections are based on "Point-in-space" pipetting technology aligned with CSLI guidelines.	Same
Operating Environment	Operating Software, Computer Console with Single User Interface	Same
System	The core Power Processor System is	Control unit, operator

Aspect/ Characteristic	Device	Predicate
Modules	comprised of a line controller computer, a system console with PrepLink™ software, inlet module, hematology module, centrifugation module, decapper module, track transport system, and output module. The Generic Connection module is an optional module to enable analyzer connectivity.	interface, sample input/output module, decapping module, track transport module. The centrifugation module is optional, and the STM device is an optional module to enable analyzer connectivity.
Sample Identification	Identification of patient tubes and sample programming using bar codes. Does not use Radio Frequency Identification Device (RFID) sample identification.	Positive sample identification via a barcode reader and RFID chip.
Sample Handling	The ability to interface with a LIS device to receive patient identification and test requests via a communications protocol to provide sample tracking via bar code labeling.	Same

K. Standard/Guidance Document Referenced (if applicable):

- IEC 61326-2-6 IEC: Electrical equipment for measurement, control and laboratory use - EMC requirements - Part 2-6: Particular requirements - In vitro diagnostic (IVD) medical equipment. 12/15/2005
- AUTO5-A CSLI: Laboratory Automation: Electromechanical Interfaces; Approved Standard. 3/1/2001

L. Test Principle:

Paramagnetic particle solid phase and chemiluminescent detection with an automated sample handling system

M. Performance Characteristics (if/when applicable):

Assay performance characteristics were established in Beckman Coulter Access® Ferritin Assay k926221, Beckman Coulter Access® Folate Assay k060774, Beckman Coulter Access® HYPERsensitive hTSH Assay k042281, Beckman Coulter Access® Vitamin B12 Assay k955436.

1. <u>Analytical performance:</u>
   a. *Precision/Reproducibility:*
      Provided in above referenced assay 510(k)'s

   b. *Linearity/assay reportable range:*
      Provided in above referenced assay 510(k)'s

   c. *Traceability, Stability, Expected values (controls, calibrators, or methods):*
      Provided in above referenced assay 510(k)'s

d. *Detection limit:*
Provided in above referenced assay 510(k)'s

e. *Analytical specificity:*
Provided in above referenced assay 510(k)'s

f. *Assay cut-off:*
Provided in above referenced assay 510(k)'s

2. Comparison studies:

a. *Method comparison with predicate device:*
In order to establish equivalence to manually introduced samples to the analyzer verses automated sample introduction and identification to the analyzer a method comparison was performed using the above referenced assays. The method comparison study employed paired sample testing and Deming regression analysis to assess the data. The assay test menu was selected by the evaluator and specimen selection was based on the site test requests. In the study, two blood samples were drawn from each patient. One sample tube was processed through the laboratory protocol using the Power Processor System with Generic Connection Module interface to the DxI 800 analyzer, and the other tube was processed on the AutoMate system and manually loaded on the analyzer.

The Deming regression analysis demonstrates comparable performance across the range of sample concentrations tested for each representative assay.

DxI assay (manual sample processing)	Sample Range	N	Slope	Intercept	r	Comparative Method
Vitamin B12	94 -671	101	0.912	23.88	0.983	DxI 800 Analyzer w/ automated sample processing (Power Processor w/ Generic Connection Module)
Ferritin	3 - 993	101	1.042	-4.37	0.995	
Folate	11 - 42	85	0.944	1.19	0.982	
Hypersensitive TSH	0.46 – 12.09	104	1.005	0.01	0.994	

The sponsor's evaluator determined the test results showed no clinically significant difference in assay performance between the two sample processing methods. This data demonstrates substantial equivalence between DxI 800 System with Power Processor connection and the predicate stand-alone analyzer.

b. Matrix comparison:
Provided in above referenced assay 510(k)'s

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):
   Provided in above referenced assay 510(k)'s

4. Clinical cut-off:
   Not Applicable

5. Expected values/Reference range:
   Provided in above referenced assay 510(k)'s

N. Instrument Name:

Power Processor Sample Processing System with Generic Connection Module

O. System Descriptions:

1. Modes of Operation:

   The Power Processor system can consist of the following interfaces: Instrument Manager, PrepLink, and Line Control Computer. The LIS sends sample programming to the PrepLink through the optional Instrument Manager in some software setups. Sample programming information is used to determine where to sort sample tubes. The Instrument Manager consolidates multiple sample programming requests for each sample tube, allowing the Power Processor system to sort sample tubes to the appropriate racks.

   The PrepLink receives sample programming information which is used to determine the routing information when queried by the Line Control Computer. PrepLink sorts sample tubes to racks based on sample programming and rack configurations specified by the operator during setup.

   The Line Control software communicates with the PrepLink software to keep track of sample tubes on the Power Processor system. The Line Control software sends and receives information from the PrepLink software and the Power Processor track. This information is contained in the Systems Error Log and the Operations Error Log (both can be used to evaluate and correct processing problems). The Line Control Computer Main screen displays a graphical representation of the automation line.

The Power Processor can be configured with optional hardware to automatically load centrifuged and decapped sample tubes onto Beckman Coulter's 800 DxI System. The Connection Modules operate identically and are designed to support an onboard sampling mechanism, where the sample tubes are transferred directly to the connected analyzer sample load area and read by the system barcode reader.

The Power Processor can be configured with optional software and hardware to allow processing of sample tubes on Connection Instrument. The Power Processor performs all pre-analytical sample tube preparation, and then sorts the sample tubes directly to Connection Module where the samples are pipetted for testing. After the samples are pipetted, the tubes can route to other instruments for additional testing or to Outlet Racks. Routing decisions are made by the PrepLink, and are based on the sample programming of each sample tube, the availability of the Connection instrument, and configuration parameters set by the operator.

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:

   Bar code

4. Specimen Sampling and Handling:

   On the DxI 800 connection, the Connection Module reads the sample bar code read prior to releasing the sample from the aspiration point, resulting in the following sequence from the DxI perspective:

   - Read sample data
   - Verify sample data matches software queue
   - Aspirate sample from tube
   - Read sample data again
   - Does sample data read before and after aspiration match? If Yes, keep sample and perform analysis; if No, discard sample and do not perform analysis
   - Release Sample from Aspiration point

5. Calibration:

   Provided in k023764

6. Quality Control:

   Provided in k023764

P. Other Supportive Instrument Performance Characteristics Data Not Covered In The "Performance Characteristics" Section above:

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.