K110413

Summary of Safety & Effectiveness
Power Processor Sample Processing System
with Generic Connection Module V5.0

MAY 11 2011

1.0 **Submitted By:**

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2.0 **Date Submitted:**

April 13, 2011

3.0 **Device Name(s):**

3.1 **Proprietary Names**
Power Processor Sample Processing System with Generic Connection Module

3.2 **Common Name**
Laboratory Automation System

3.2 **Classification Name**
Discrete photometric chemistry analyzer for clinical use (862.2160)

4.0 **Predicate Device:**

The Power Processor Sample Processing System with Generic Connection Module Software Version 5.0 claims substantial equivalence to the Power Processor Sample Processing System with Generic Connection Module currently in commercial distribution, FDA 510(k) Number K090588.

Candidate(s)	Predicate	Manufacturer	Docket Number
Power Processor Sample Processing System with Generic Connection Module Software Version 5.0	Power Processor Sample Processing System with Generic Connection Module Software Version 3.5	Beckman Coulter, Inc	K090588

5.0 **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, including Beckman Coulter and third party systems. 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. This method is used to establish connection with Beckman Coulter's Synchron LX® and UniCel® DxC Systems and some third party analyzers.

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.

6.0 **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 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 600/800 Access Immunoassay System(s) 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 600/800 System(s) 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 600/800 System(s) 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 HYPERsensitive 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.

7.0 Comparison to the Predicate:
(Description of the Modification to the Legally Marketed Device)

The modification to the Power Processor Sample Processing System with Generic Connection Module involves upgrading the PrepLink Software from Version 3.5 to Version 5.0.

PrepLink Version 5.0 provides the following key software features:

- Allow the system to connect up to 12 generic connections (increase from current 4), and up to 4 Beckman Coulter (SYNCHRON LX/UniCel DxC) analyzer connections (remains unchanged).
- Provide an option to increase the primary sample ID to 13 characters, plus 2 characters for the secondary sample ID.
- Provide an option to connect up to three 3K or three 5K tube stockyards.
- Provide an option for load balancing number of tubes per rack instead of round robin of one tube for each analyzer. Round robin (RR) is one of the simplest scheduling algorithms for processes in an operating system, which assigns time slices to each process in equal portions and in circular order, handling all processes without priority.
- Provide Data Migration Utility (DMU) for V3.5/V3.6 to V5.0.
- Provide an option to route a primary tube with no assigned tests in its test order to the stockyard.
- Provide an option to backup/restore the data files on USB drives.

8.0 Summary of Performance Data:

Performance data from validation testing shows that all software design, development and verification activities have been completed and passed, and supports equivalency of Power Processor V5.0 to Power Processor V3.5.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993

MAY 1 1 2011

Beckman Coulter, Inc.
c/o Marine Boyajian
Senior Regulatory Affairs Specialist
250 South Kraemer Blvd,
Brea, CA 92822

Re: k110413
Trade/Device Name: Power Processor Sample Processing System with Generic Connections
Regulation Number: 21CFR Sec.-862.1810
Regulation Name: Vitamin B12 test system.
Regulatory Class: II
Product Code: CDD, DBF, CGN, JLW, JJE
Dated: April 13, 2011
Received: April, 14, 2011

Dear: Ms. Boyajian:

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 Parts 801 and 809), 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 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) 796-7100 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Courtney 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): K110413

Device Name: Power Processor Sample Processing System with Generic Connection Module and Access Immunoassay System Reagents

Indication 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.

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

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

510(k)___K110413_____

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(21 CFR Part 801 Subpart D) (21 CFR Part 801 Subpart C)

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