Summary of Safety & Effectiveness
SYNCHRON® Systems
Enzymatic Creatinine (CR-E) Reagent

K093458

1.0 **Submitted By:**

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Beckman Coulter, Inc.
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DEC - 4 2009

2.0 **Date Submitted:**

November 04, 2009

3.0 **Device Name(s):**

3.1 **Proprietary Names**
SYNCHRON® Systems Enzymatic Creatinine (CR-E) Reagent

3.2 **Classification Name**
Enzymatic Method Creatinine (21 CFR § 862.1225)

4.0 **Predicate Device:**

The SYNCHRON Systems Enzymatic Creatinine (CR-E) Reagent claims substantial equivalence to the Beckman Coulter SYNCHRON Systems Enzymatic Creatinine (CR-E) reagent currently in commercial distribution, FDA 510(k) Number K091742.

Candidate(s)	Predicate	Manufacturer	Docket Number
SYNCHRON Systems Enzymatic Creatinine (CR-E) Reagent	SYNCHRON Systems Enzymatic Creatinine (CR-E) Reagent	Beckman Coulter, Inc	K091742

5.0 **Description:**

CR-E reagent is used to measure the creatinine concentration by an enzymatic method. This enzymatic creatinine method utilizes a multi-step approach ending with a photometric end-point reaction.
The SYNCHRON Enzymatic Creatinine (CR-E) Reagent is designed for optimal performance on the SYNCHRON LX®, UniCel® DxC 600/800, and SYNCHRON CX® PRO Clinical Systems. The reagent kit contains two 200-test cartridges that are packaged separately from the associated calibrator.

6.0 **Intended Use:**

CR-E reagent, when used in conjunction with SYNCHRON® System(s), UniCel® DxC System(s) and SYNCHRON® Systems AQUA CAL 1 and 2 and SYNCHRON CX® Calibrator Level 1 and 2, is intended for the quantitative determination of creatinine (CR-E) concentration in human serum, plasma or urine (urine is not available on the SYNCHRON CX® PRO Systems).

Creatinine measurements are used in the diagnosis and treatment of renal diseases, in monitoring renal dialysis, and as a calculation basis for measuring other urine analytes.

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

The modification to the SYNCHRON Systems CR-E assay involves extending the Limit of Detection (Beckman Coulter uses the term Analytical Sensitivity to characterize Limit of Detection in its product labeling) to 0.1 mg/dL for serum samples. The Limit of Detection for urine samples remains unchanged.
The current claimed Analytical Sensitivity for creatinine determination by the CR-E assay (cleared under FDA 510(k) Number K091742) is 0.2 mg/dL for serum and 10 mg/dL for urine (on SYNCHRON LX/UniCel DxC Clinical Systems only).

8.0 **Summary of Performance Data:**

Performance data from validation testing supports equivalency.

DEPARTMENT OF HEALTH & HUMAN SERVICES

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

Beckman Coulter, Inc.
c/o Ms. Marine Boyajian
Senior Regulatory Affairs Specialist
200 S. Kraemer Blvd., M/S W-110
Brea, CA 92822-8000

DEC 4 2009

Re: k093458
Trade Name: SYNCHRON Systems Enzymatic Creatinine (CR-E) Reagent
Regulation Number: 21 CFR §862.1225
Regulation Name: Creatinine Test System
Regulatory Class: Class II
Product Codes: JFY
Dated: November 4, 2009
Received: November 6, 2009

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 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): K093458

Device Name: SYNCHRON® Systems Enzymatic Creatinine (CR-E) Reagent

Indication For Use:

CR-E reagent, when used in conjunction with SYNCHRON® Systems, UniCel® DxC Systems and SYNCHRON® Systems AQUA CAL 1 and 2 and SYNCHRON CX® Calibrator Level 1 and 2, is intended for the quantitative determination of creatinine (CR-E) concentration in human serum, plasma or urine (urine is not available on the SYNCHRON CX® PRO Systems).

Creatinine measurements are used in the diagnosis and treatment of renal diseases, in monitoring renal dialysis, and as a calculation basis for measuring other urine analytes.

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)

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

510(k) K093458