K071280

510(k) Summary

JUN - 1 2007

1.0 Submitted By:

Tara M. Viviani
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Beckman Coulter, Inc.
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Brea, CA 92822-8000
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2.0 Date Submitted

May 4, 2007

3.0 Device Name(s):

3.1 Proprietary Names

SYNCHRON® CX Delta Clinical System
SYNCHRON® CX Calibrator 1, 2 &3

3.2 Classification Names

Creatinine test system (21 CFR § 862.1225)
Calibrator, Multi-Analyte Mixutre (21 CFR § 862.1150)

4.0 Legally Marketed Device

The SYNCHRON CX Delta Clinical Systems, claims substantial equivalence to the Beckman Coulter SYNCHRON CX Delta Clinical System currently in commercial distribution, FDA 510(k) Number K950958.

5.0 Device Description

The SYNCHRON CX Delta System determines creatinine concentration by means of the Jaffe rate method. A precise volume of sample is injected into the reaction cup with CRE3 reagent containing picric acid. Absorbance readings are taken at 520 nm between 19 to 25 seconds after sample introduction. The SYNCHRON CX Delta System utilizes a two level calibrator for the creatinine test. SYNCHRON CX

Calibrator is designed for optimal performance on the SYNCHRON CX Delta Clinical Systems. CX Calibrator is an aqueous based calibrator made by New England Reagent Laboratory (NERL) to Beckman Coulter specifications. This product is tested during manufacturing using standards traceable to National Institute of Standard and Technology (NIST) reference materials. The creatinine concentrations are established based on addition of weighed-in specific quantities of creatinine to achieve the appropriate level of each calibrator. Each calibrator level is packaged individually in 25 mL bottles, 6 to a package.

6.0 Intended Use

CRE3 reagent, when used in conjunction with SYNCHRON CX® Delta System(s) SYNCHRON® Systems CX Calibrator 1 and 2, is intended for the quantitative determination of Creatinine (CRE3) in human serum, plasma or urine.

Beckman Coulter SYNCHRON CX Calibrators 1, 2, and 3 are to be used for calibrating SYNCHRON CX Delta, CX® CE, and CX PRO Systems only.

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

The modification to the creatinine module (CRE3) involves modification of the calibrator set points coded in the chemistry database. No formulation changes or system parameters have been modified with the exception of the calibrator set points. The modification to the CX Calibrator 1, 2 & 3 set points involves value assignment of the creatinine levels to values determined by a one time correlation of serum creatinine sample set to Isotope Dilution Mass Spectometery (IDMS). These new calibrator set points will replace the current values contained in the in the chemistry database. The product will continue to be manufactured in the same

manner as it is today. The creatinine level in each calibrator will still be based on addition of weighed-in specific values of creatinine.

8.0 Summary of Performance Data

Performance data from validation testing supports equivalency.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

JUN - 1 2007

Beckman Coulter, Inc.
c/o Ms. Tara M. Viviani,
Senior Regulatory Affairs Specialist
200 South Kraemer Blvd., M/S W-110
Brea, CA 92821

Re: k071280
Trade/Device Name: Synchron® CX Delta Clinical Systems
Regulation Number: 21 CFR§ 862.1225
Regulation Name: Creatinine Test System
Regulatory Class: Class II
Product Code: CGX, JIX
Dated: May 04, 2007
Received: May 07, 2007

Dear Ms. Viviani:

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); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820).

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific information about the application of labeling requirements to your device, or questions on the promotion and advertising of your device, please contact the Office of In Vitro Diagnostic Device Evaluation and Safety at (240) 276-0490. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). 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 (240) 276-3150 or at its Internet address at http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Jean M. Cooper, M.S., D.V.M.

Jean M. Cooper, M.S., D.V.M.
Director
Division of Chemistry and Toxicology
Office of *In Vitro* Diagnostic Device
Evaluation and Safety
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K071280

Device Name: **SYNCHRON® CX Delta Clinical Systems, Creatinine Test Systems**

Indications for Use:
Beckman Coulter SYNCHRON CX Calibrators 1, 2, and 3 are to be used for calibrating SYNCHRON CX Delta, CX® CE, and CX PRO Systems only.

CRE3 reagent, in conjunction with SYNCHRON CX® Delta Systems and SYNCHRON CX® Calibrators 1, 2 and 3 is intended for the quantitative determination of Creatinine (CRE3) in human serum, plasma or urine.

CLINICAL SIGNIFICANCE

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 ✓ AND/OR Over-the-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

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

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

Division Sign-Off

Office of In Vitro Diagnostic
Device Evaluation and Safety

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