K 110251

MAY 25 2011

BECKMAN COULTER

Summary of Safety & Effectiveness
SYNCHRON® Systems
SYNCHRON Multi Calibrator

This summary of safety and effectiveness is being submitted in accordance with the requirements of the Safe Medical Device Act of 1990 and the implementing regulation 21 CFR 807.92.

1.0 **Submitted By:**

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2.0 **Date Submitted:**

January 26, 2011 and May 5, 2011

3.0 **Device Name(s):**

3.1 **Proprietary Names**
SYNCHRON Multi Calibrator

3.2 **Classification Name**
Calibrator, Secondary or Multi-Analyte Mixture (Product Code – JIT/JIX), 21 CFR.1150, Class II, (75)

4.0 **Predicate Device:**

Candidate(s)	Predicate	Manufacturer	Docket Number
SYNCHRON Multi Calibrator	SYNCHRON Multi Calibrator	Beckman	K883181

5.0 **Description:**

This is a liquid, ready-to-use, multi analyte, IVD calibrator. The SYNCHRON Multi Calibrator is prepared in a human serum matrix which is stabilized by the use of ethylene glycol. During manufacture, the multiple constituents are spiked into the matrix at the desired concentration levels. The analyte(s) in this calibrator is traceable using prEN ISO 17511 to the reference materials listed below.

Measurand	Traceable To
ALB	NIST 927a'
CA	NIST SRM 915
CHOL	NIST 911b
GLU	NIST SRM 917a
Lactate	Manufacturer's working calibrator
MG	NIST SRM 929
PHOS	NIST SRM 3139a
PHS	NIST SRM 3139a
PO4	NIST SRM 3139a
TP	NIST SRM 927a
TG, TG-B	Manufacturer's working calibrator
UREA	NIST SRM 912a
BUN	NIST SRM 912a
URIC	NIST SRM 913b

Value assignment and stability data is available with Beckman Coulter.

6.0 **Intended Use:**

The SYNCHRON MULTI CALIBRATOR, used in conjunction with SYNCHRON reagents, is intended for use on SYNCHRON Systems for the calibration of Albumin, Blood Urea Nitrogen (Urea), Calcium, Cholesterol, Glucose, Inorganic Phosphorus, Lactate, Magnesium, Total Protein, Triglycerides, and Uric Acid.

7.0 **Comparison to Predicate(s):**

The following table shows similarities and differences between the primary predicate identified in Section 4.0 of this summary.

List of design inputs that are the same between the two devices

	Predicate Device: SYNCHRON Multi Calibrator	**Proposed Device: SYNCHRON Multi Calibrator**
Intended Use	The Beckman CX MULTI CALIBRATOR, in conjunction with SYNCHRON CX reagents, is intended for use on SYNCHRON CX4 and CX5 Systems for the calibration of Albumin, Blood Urea Nitrogen (Urea), Calcium, Cholesterol, Creatinine, Glucose, Inorganic Phosphorus, Total Protein, Triglycerides, and Uric Acid.	The SYNCHRON MULTI CALIBRATOR, used in conjunction with SYNCHRON reagents, is intended for use on SYNCHRON Systems for the calibration of Albumin, Blood Urea Nitrogen (Urea), Calcium, Cholesterol, Glucose, Inorganic Phosphorus, Lactate, Magnesium, Total Protein, Triglycerides, and Uric Acid.
Matrix base	The calibrator is prepared from human serum and stabilized by the use of ethylene glycol.	The calibrator is prepared from human serum and stabilized by the use of ethylene glycol.
Levels	1	1
Form	Liquid, ready to use	Liquid, ready to use
Open vial stability	20 days at +2°C to +8°C	20 days at +2°C to +8°C
Storage	-15°C to -20°C	-15°C to -20°C
Packaging	6 X 20 mL bottles	6 X 20 mL bottles
Real time stability	24 months	24 months

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List of design inputs that are different between the two devices

Differences	**Predicate Device: SYNCHRON Multi Calibrator**	**Proposed Device: SYNCHRON Multi Calibrator**
Value assigned analytes	Albumin, Blood Urea Nitrogen (Urea), Calcium, Cholesterol, Creatinine, Glucose, Inorganic Phosphorus, Total Protein, Triglycerides, and Uric Acid.	Albumin, Blood Urea Nitrogen (Urea), Calcium, Cholesterol, Glucose, Inorganic Phosphorus, **Lactate, Magnesium**, Total Protein, Triglycerides, and Uric Acid.
Formulation: Multiple constituents	Albumin, Blood Urea Nitrogen (Urea), Calcium, Cholesterol, Creatinine, Glucose, Inorganic Phosphorus, Lactate, Magnesium, Total Protein, Triglycerides, Uric Acid and Iron (not value assigned).	Albumin, Blood Urea Nitrogen (Urea), Calcium, Cholesterol, Glucose, Inorganic Phosphorus, Lactate, Magnesium, Total Protein, Triglycerides, and Uric Acid; Includes also, Creatinine, Iron, Salicylate and Alkaline Phosphatase (not value assigned analytes).

8.0 Summary of Performance Data:

The data in the Premarket Notification on safety and effectiveness supports a finding of substantial equivalence to the predicate which is an existing multi calibrator already in commercial distribution with well established use and robustness. Equivalence is demonstrated through device comparisons, traceability information, value assignment practices and stability experiments.

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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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

Beckman Coulter, Inc.
c/o Yvette Lloyd
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Re: k110251

Trade/Device Name: SYNCHRON Systems SYNCHRON Multi Calibrator
Regulation Number: 21 CFR 862.1150
Regulation Name: Calibrator, Multi-Analyte Mixture
Regulatory Class: Class II
Product Code: JIX
Dated: 13 Apr 2011
Received: 15 Apr 2011

MAY 25 2011

Dear: Ms. Lloyd,

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 class II (Special Controls), 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). 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 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

Attachment A:

Indications for Use Form

510(k) Number (if known): K110251

Device Name: SYNCHRON® Systems SYNCHRON MULTI CALIBRATOR

Indications for Use:

The SYNCHRON MULTI CALIBRATOR, used in conjunction with SYNCHRON reagents, is intended for use on SYNCHRON Systems for the calibration of Albumin, Blood Urea Nitrogen (Urea), Calcium, Cholesterol, Glucose, Inorganic Phosphorus, Lactate, Magnesium, Total Protein, Triglycerides, and Uric Acid.

Prescription Use X (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

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

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

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

510(k) K110251

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