



JUL 1 1 2014

K141388

510k Summary System Calibrator

1.0

Submitted By:

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2.0 **Date of preparation:**

May 23rd, 2014

3.0 **Device Name(s):**

Proprietary Names: System Calibrator
Common Name: System Calibrator
Classification: 862.1150
Product Code: JIX

3.2 **Classification Name**
Calibrator (21 CFR § 862.1150)

4.0 **Predicate Device:**

Candidate(s)	Predicate	Manufacturer	Docket Number
System Calibrator 66300	SYNCHRON® Enzyme Validator 441350	Beckman Coulter	K951964

The System calibrator is substantially equivalent to the Beckman Coulter product listed above currently in commercial distribution.

5.0 **Description:**

The System calibrator kit is a lyophilized human serum based product intended to provide calibration for AU Enzyme reagents (ALP, ALT, AST, Amylase, CK-NAC, GGT and LDH) for the quantitative determination of the relevant analyte on Beckman Coulter AU analyzers.

The following is the kit configuration for the system calibrator:
66300 kit has 20 vials with 5 ml contents for Level 1.

The System calibrator is designed for optimal performance on Beckman Coulter AU analyzers.

The System calibrator contains lyophilized human serum with chemical additives, preservatives, and enzymes of human, animal and plant origin.

Biological materials of human origin contained in this product were tested for Anti-HCV, HbsAg and Anti-HIV 1/2 on a single donor basis using FDA approved methods and was found to be non-reactive. As there is no known test method that can offer complete assurance that products derived from human blood will not transmit infectious agents, this product should be handled as a potentially infectious material.

6.0 Intended Use:

The System Calibrator is a calibration serum intended to be used for the calibration of ALP, ALT, AST, Amylase, CK-NAC, GGT and LDH enzymes on Beckman Coulter AU480, AU680 and AU5800 analysers.

.For In Vitro Diagnostic use only.

7.0 Comparison to Predicate(s):

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

Similarities		
Feature	System Calibrator	SYNCHRON® Enzyme Validator
Intended Use	The System Calibrator is a calibration serum intended to be used for the calibration of ALP, ALT, AST, Amylase, CK-NAC, GGT and LDH enzymes on Beckman Coulter AU480, AU680 and AU5800 analysers.	The SYNCHRON Enzyme Validator Set, in conjunction with specified enzyme assays on SYNCHRON® Systems, is intended to provide points of reference in the measurement of selected human enzymes.
Analyte Constituents	Alkaline Phosphatase Alanine Aminotransferase Amylase Aspartate Aminotransferase Creatinine Kinase Gamma glutamyl transferase Lactate Dehydrogenase	Alkaline Phosphatase Alanine Aminotransferase Amylase Aspartate Aminotransferase Creatinine Kinase Cholinesterase Gamma glutamyl transferase Lipase Lactate Dehydrogenase
Matrix Base	Human Serum	Human Serum

Differences		
Feature	System Calibrator	SYNCHRON® Enzyme Validator
Form	Lyophilized human serum	Liquid
Levels	1 Level	2 Levels
Volume	20 x 5 ml	3 x 5ml of each level/kit.
Storage (Closed/ Shelf Life)	36 months	16 months
Open Vial	8 hours @ 2-8°C	60 days @ -15°C - -20°C
Traceability	Theoretical Extinction Co-efficient	IFCC method, DGKCh method and Manufacturers working calibrator

8.0 Performance Characteristics summary report as per FDA guidance “Abbreviate 510 (k) submissions for In Vitro Diagnostic Calibrators”

8.1 Stability testing summary

Stability studies have been performed to determine the open vial stability and shelf life for this calibrator. For Open Vial and Shelf Life Stability studies, Beckman Coulter utilized internal test procedures from CLSI EP25A entitled “Evaluation of stability of In Vitro diagnostic reagents”.

Open vial Testing was performed using 3 individual calibrator lots and multiple time points throughout the open vial stability claim period on a representative AU Clinical Chemistry analyzer platform.

At each time point the test vial was run with freshly opened calibrator vial. 2 Levels of an appropriate control material were used to control the runs. All were tested in replicated of 5 at each time point. A maximum allowable drift of ±5% was applied

Open Vial stability:

- 8 hours @ 2-8°C

Shelf Life stability testing was carried out utilizing EP25A in order to support shelf life storage claim of 36 months when stored at 2-8°C. Shelf Life stability testing was performed on 3 individual lots of calibrator at multiple time points. All testing was conducted on a representative AU Clinical Chemistry analyzer platform with the associated reagent test system. A maximum allowable drift of ±5% was applied. To ensure robustness of the shelf life claim the shelf life period was tested for 36 months plus at least one month after expire date claim.

Shelf Life stability:

- 36 months @ 2-8°C

7.1 Value Assignment Summary

Value assignment testing was performed utilizing internal procedures and protocols to determine values that will be used to calibrate AU enzyme reagents as per IFU on Beckman Coulter AU480/680/5800 Clinical chemistry analyzer platforms. Multiple reagent lots and calibrator vials

were used to incorporate reagent and calibrator variation. 10 replicates from 8 runs were performed to give a total of 80 data points per each individual reagent. Distinct runs with minimum gaps of 2 hours were performed and 8 calibration events were used to incorporate variation from calibration and environmental sources. The overall mean was calculated for each individual enzyme and assigned as the calibrator set point.

7.2 Traceability Summary

The System calibrator (66300) values were assigned using theoretical MB Factors. The calibration of each reagent is therefore traceable to the theoretical extinction coefficient as detailed on the individual reagent IFU's and in Table below:

Product	Theoretical Extinction Co-efficient
Amylase OSR6x06	11320
ALP OSR6x04	17900
ALT OSR6x07	4960
AST OSR6x09	4960
GGT OSR6x19	7453
LDH OSR6x27	4960
CK-NAC OSR6x79	6300

8.0 Conclusion:

The conclusions drawn from the nonclinical tests (discussed above) demonstrate that the System calibrator 66300 is as safe, as effective and performs as well as the predicate device. The submitted information in this premarket notification is complete and supports a substantial equivalence decision.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

July 11, 2014

BECKMAN COULTER IRELAND INC
DAVID DAVIS
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BREA CA 92821

Re: K141388

Trade/Device Name: System Calibrator
Regulation Number: 21 CFR 862.1150
Regulation Name: Calibrator
Regulatory Class: II
Product Code: JIX
Dated: May 23, 2014
Received: May 27, 2014

Dear Mr. David Davis:

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. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. 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); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Page 2—Mr. Davis

If you desire specific advice for your device on our labeling regulations (21 CFR Parts 801 and 809), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address

<http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>. 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 Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address

<http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,

Courtney H. Lias -S

Courtney H. Lias, Ph.D.
Director
Division of Chemistry and Toxicology Devices
Office of In Vitro Diagnostics
and Radiological Health
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Form Approved: OMB No. 0910-0120

Expiration Date: January 31, 2017

See PRA Statement below.

Indications for Use

510(k) Number (if known)

k141388

Device Name

System Calibrator

Indications for Use (Describe)

The System Calibrator is a calibration serum intended to be used for the calibration of ALP, ALT, AST, Amylase, CK-NAC, GGT and LDH enzymes on Beckman Coulter AU480, AU680 and AU5800 analysers.

For In Vitro Diagnostic use only.

Type of Use (Select one or both, as applicable)

Prescription Use (Part 21 CFR 801 Subpart D)

Over-The-Counter Use (21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) (Signature)

Yung W. Chan -S

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