K994169

FEB 3 2000

BECKMAN COULTER

Summary of Safety & Effectiveness
SYNCHRON® CX Systems Prealbumin Calibrator

1.0 **Submitted By:**

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Beckman Coulter, Inc.
200 S. Kraemer Blvd., W-104
Brea, California 92822-8000
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2.0 **Date Submitted:**

December 6, 1999

3.0 **Device Name(s):**

3.1 **Proprietary Names**

SYNCHRON® CX Systems Prealbumin Calibrator

3.2 **Classification Name**

Calibrator, (21 CFR §862.1150)

4.0 **Predicate Device(s):**

SYNCHRON Systems Reagent	Predicate	Manufacturer	Docket Number
SYNCHRON® Systems PAB Calibrator	Beckman Immunochemistry Systems CAL 3	Beckman Coulter, Inc.	K854811

5.0 **Description:**

The SYNCHRON CX Systems Prealbumin Calibrator Set is a six level ready-to-use human serum-based liquid calibrator set manufactured by Beckman Coulter, Inc. Each kit contains 1 X 3 mL bottles of a specific level of calibrator (identified as Levels 1 to Level 6).

5.0 **Intended Use:**

The SYNCHRON® CX Systems Prealbumin Calibrator is intended for use with the SYNCHRON CX Systems for the calibration of Prealbumin (PAB) reagent.

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

Reagent	Aspect/Characteristic	Comments
SYNCHRON Systems CX PAB Calibrator	Source Material: Fresh frozen human plasma that has been defibrinated and processed.	Same as Beckman CAL 3
	Storage Temperature (+2°C to +8°C)	
	Liquid, ready-to-use form	
	Value Assignment Methodology	
	Traceable to the IFCC reference preparation for plasma proteins, lot CRM 470.	

Reagent	Aspect/Characteristic	Comments
SYNCHRON Systems PAB Calibrator	Intended Use:	SYNCHRON CX Systems PAB Calibrator is intended for use in calibration of SYNCHRON CX Systems Prealbumin Reagent. Beckman CAL 3 is intended for use in calibration of albumin and prealbumin on ARRAY®, ARRAY® 360, and IMMAGE™ Immunochemistry systems
	Levels of Analyte	SYNCHRON Systems PAB Calibrator: 6 levels Beckman CAL 3: 1 level

8.0 **Summary of Performance Data:**

The data in the Premarket Notification on safety and effectiveness supports a finding of substantial equivalence to products already in commercial distribution. Stress stability studies of the Prealbumin calibrator support the Beckman stability claim of 24 months.

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.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

FEB 3 2000

Ms. Lucinda Stockert
Staff Regulatory Specialist
Beckman Coulter, Inc.
200 S. Kraemer Boulevard
M/S W-104
Box 8000
Brea, California 92822-8000

Re: K994169
Trade Name: SYNCHRON® CX Systems Prealbumin Calibrator
Regulatory Class: II
Product Code: JIS
Dated: December 6, 1999
Received: December 10, 1999

Dear Ms. Stockert:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we 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). 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 (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 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 Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4588. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Steven Gutman

Steven I. Gutman, M.D., M.B.A.
Director
Division of Clinical Laboratory Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

510(k) Number (if known): K994169

Device Name: **SYNCHRON® CX Systems Prealbumin Calibrator**

Indications for Use:

The SYNCHRON® CX Systems Prealbumin Calibrator, used in conjunction with SYNCHRON® Systems Prealbumin reagent, is intended for use on Beckman's SYNCHRON CX Systems for the calibration of prealbumin test systems.

Clinical Significance:

A calibrator is a device intended for medical purposes for use in a test system to establish points of reference that are used in the determination of values in the measurement of substances in human specimens.

Jean Cooper

(Division Sign-Off)
Division of Clinical Laboratory Devices
510(k) Number K994169

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-the-Counter Use _____
(per 21 CFR 801.109) Optional Format 1-2-96