

FEB 3 2000

1K994168



Summary of Safety & Effectiveness
SYNCHRON® LX Systems Prealbumin Calibrator

1.0 **Submitted By:**

Lucinda Stockert
Staff Regulatory Specialist, Product Submissions
Beckman Coulter, Inc.
200 S. Kraemer Blvd., W-104
Brea, California 92822-8000
Telephone: (714) 961-3777
FAX: (714) 961-4123

2.0 **Date Submitted:**

December 6, 1999

3.0 **Device Name(s):**

3.1 **Proprietary Names**

SYNCHRON® LX 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 Systems Prealbumin Calibrator is a ready-to-use human serum-based liquid calibrator manufactured by Beckman Coulter, Inc. Each kit contains 1 X 3 mL bottles of the calibrator.

Beckman Coulter, Inc.
200 S. Kraemer Boulevard
Brea, CA 92821

Mailing Address:
200 S. Kraemer Boulevard
P.O. Box 8000
Brea, CA 92822-8000

Telephone: (714) 993-5321
Facsimile: (714) 961-4165
Internet: www.beckmancoulter.com

5.0 Intended Use:

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

7.0 Comparison to Predicate(s):

| Reagent | Aspect/Characteristic | Comments |
|------------------------------------|--|-----------------------|
| SYNCHRON LX Systems 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 | |
| | One level of analyte | |
| | Value Assignment Methodology | |
| | Traceable to the IFCC reference preparation for plasma proteins, lot CRM 470. | |

| Reagent | Aspect/Characteristic | Comments |
|------------------------------------|-----------------------|---|
| SYNCHRON LX Systems PAB Calibrator | Intended Use: | SYNCHRON LX Systems PAB Calibrator is intended for use in calibration of SYNCHRON LX Systems Prealbumin Reagent. Beckman CAL 3 is intended for use in calibration of albumin and prealbumin on ARRAY®, ARRAY® 360, and IMMAGE™ Immunochemistry systems |

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

FEB 3 2000

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

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

Re: K994168
Trade Name: SYNCHRON® LX 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.

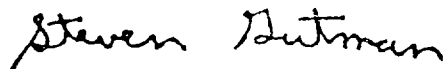
A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (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.

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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,

A handwritten signature in black ink that reads "Steven Gutman". The signature is written in a cursive style with a large initial 'S'.

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): K994168

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

Indications for Use:

The SYNCHRON® LX Systems Prealbumin Calibrator, used in conjunction with SYNCHRON® Systems Prealbumin reagent, is intended for use on Beckman's SYNCHRON LX 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 Coogan
(Division Sign-Off)
Division of Clinical Laboratory Devices
510(k) Number 994168

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓
(per 21 CFR 801.109)

OR

Over-the-Counter Use _____
Optional Format 1-2-96