K971283

JUN - 3 1997

Summary of Safety & Effectiveness
SYNCHRON ® Systems CAL 5 Plus

1.0 **Submitted By:**

Sheri Hall
Product Submissions Manager
Beckman Instruments, Inc.
200 S. Kraemer Blvd., W-337
Brea, California 92822-8000
Telephone: (714) 993-8961
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2.0 **Date Submitted:**

28 March 1997

3.0 **Device Name(s):**

3.1 **Proprietary Names**

SYNCHRON® Systems CAL 5 Plus

3.2 **Classification Name**

(21 CFR § 862.1150) Calibrator

4.0 **Predicate Device(s):**

SYNCHRON Systems CAL 5 Plus	Predicate	Predicate Company	Docket Number
SYNCHRON Systems CAL 5 Plus	Beckman CAL 5 Plus	Beckman Instruments, Inc.	K926236/A

5.0 Description:

This SYNCHRON Systems CAL 5 Plus is designed for use with clinical chemistry analyzers from Beckman Instruments, such as the SYNCHRON CX® and LX™ Clinical Systems. The SYNCHRON Systems CAL 5 Plus is for use in the calibration of SYNCHRON Systems Antistreptolysin-O (ASO-), C-reactive protein (CRP), and Rheumatoid factor (RF) chemistries.

6.0 Intended Use:

The SYNCHRON® Systems CAL 5 Plus, when used in conjunction with SYNCHRON® Systems and reagents, is intended for use in the calibration of Antistreptolysin-O (ASO-) on the SYNCHRON CX® Systems and for Antistreptolysin-O (ASO-), C-reactive protein (CRP), and Rheumatoid factor (RF) chemistries on the SYNCHRON LX™ Systems.

7.0 Comparison to Predicate(s):

The SYNCHRON Systems CAL 5 Plus is a frozen liquid human serum matrix identical to the Beckman CAL 5 Plus product. The only difference between the Beckman CAL 5 Plus and the SYNCHRON Systems CAL 5 Plus is the instrument platform on which they are used. The Beckman Immunochemistry Systems are fully automated, specific protein analyzers, that measure by nephelometry; while the SYNCHRON Systems are fully automated, clinical chemistry analyzers that measure by spectrophotometry.

8.0 Summary of Performance Data:

The data in the Premarket Notification on safety and effectiveness supports a finding of substantial equivalence of the SYNCHRON Systems CAL 5 Plus to the Beckman CAL 5 Plus and is stable for ASO, CRP, and RF. The value assignment process for each analyte is correlated to a known standard via the anchor method. The SYNCHRON Systems CAL 5 Plus value assignment and verification processes yield acceptable calibrator assigned values for calibration on the SYNCHRON LX System and SYNCHRON CX Systems.

SYNCHRON Systems CAL 5 Plus Stability Testing Summary

Stress Temperature	Duration of Incubation	Predicted Stability	Beckman Stability Claim*
32°C	40 Days	32 Months	24 Months
37°C	24 Days	33 Months	24 Months
41°C	15.5 Days	32 Months	24 Months

*** Expiration dating placed on the package based on date of manufacture**

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

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

JUN - 3 1997

Ms. Sheri Hall
Product Submissions Manager
Beckman Instruments, Inc.
200 S. Kraemer Boulevard, W-337
Brea, California 92822-8000

Re: K971283
Trade Name: SYNCHRON® Systems CAL 5 Plus
Regulatory Class: II
Product Code: JIX
Dated: April 1, 1997
Received: April 7, 1997

Dear Ms. Hall:

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 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 Good Manufacturing Practice for Medical Devices: General (GMP) regulation (21 CFR Part 820) and that, through periodic GMP 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.

Under the Clinical Laboratory Improvement Amendments of 1988 (CLIA-88), this device may require a CLIA complexity categorization. To determine if it does, you should contact the Centers for Disease Control and Prevention (CDC) at (770)488-7655.

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" (21 CFR 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 at (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/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):

Device Name: **SYNCHRON® Systems**
CAL 5 Plus

Indications for Use:

The SYNCHRON® Systems CAL 5 Plus, when used in conjunction with SYNCHRON® Systems and reagents, is intended for use in the calibration of Antistreptolysin-O (ASO-) on the SYNCHRON CX® Systems and for Antistreptolysin-O (ASO-), C-reactive protein (CRP), and Rheumatoid factor (RF) chemistries on the SYNCHRON LX™ Systems.

21 CFR § 862.1150 Calibrator

(a) Identification. 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.
(b) Classification. Class II.

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

(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