NOV 26 1999

K993473

BECKMAN COULTER

Summary of Safety and Effectiveness
SYNCHRON® Systems
Drug Calibrator 2

1.0 **Submitted By:**

Gail Lefebvre
Associate Regulatory Specialist, Product Submissions
Beckman Coulter, Inc.
200 S. Kraemer Blvd., W-104
Brea, California 92822-8000
Telephone: (714) 993-8503
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2.0 **Date Submitted:**

October 13, 1999

3.0 **Device Name(s):**

3.1 **Proprietary Names**

SYNCHRON® Systems Drug Calibrator 2

3.2 **Classification Name**

Clinical Toxicology Calibrator (21 CFR § 862.3200)

4.0 **Predicate Device(s):**

SYNCHRON Systems Reagent	Predicate	Manufacturer	Docket Number
SYNCHRON® Systems Drug Calibrator 2	SYNCHRON® Drug Calibrator 2	Beckman Coulter, Inc.	K982935

5.0 **Description:**

The SYNCHRON® Systems Drug Calibrator 2 is intended for use on SYNCHRON Systems for the calibration of digoxin and acetaminophen. This product contains a 2.0 mL bottle each of Levels 1 to 6 of Drug Calibrator 2. The storage temperature for the calibrator is +2°C to +8°C.

6.0 Intended Use:

The Beckman Coulter Drug Calibrator 2 is a six-level calibrator intended for use on the SYNCHRON CX Systems and LX20 Systems for the calibration of digoxin and acetaminophen.

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

The digoxin level between the two products is identical. Both the candidate and the predicate are made from human serum to which weighed-in quantities of digoxin analyte are added.

8.0 **Summary of Performance Data:**

The new Drug Calibrator 2 product contains acetaminophen analyte.

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

NOV 26 1999

Ms. Gail Lefebvre
Associate Regulatory Specialist
Beckman Coulter Inc.
200 S. Kraemer Boulevard
Brea, California 92821

Re: K993473
Trade Name: SYNCHRON® Systems Drug Calibrator 2
Regulatory Class: II
Product Code: DLJ
Dated: October 13, 1999
Received: October 14, 1999

Dear Ms. Lefebvre:

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.

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 (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): K993493

Device Name: **SYNCHRON® Systems Drug Calibrator 2**

Indications for Use:

The Beckman Coulter Drug Calibrator 2 is a six-level calibrator intended for use on the SYNCHRON CX Systems and LX20 Systems for the calibration of digoxin and acetaminophen.

Clinical Significance:
The Drug Calibrator 2 utilizes processed human serum to which weighed-in drug quantities are added. The calibrator set is designed for generation of a six-point calibration curve which defines the analytical range for digoxin and acetaminophen.

Susan Cooper
(Division Sign-Off)
Division of Clinical Laboratory Devices
510(k) Number K993493

(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