K984014

DEC 23 1998

BECKMAN COULTER

Summary of Safety & Effectiveness
SYNCHRON® Systems
Enzyme Validator Set

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
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2.0 **Date Submitted:**

November 4, 1998

3.0 **Device Name(s):**

3.1 **Proprietary Names**

SYNCHRON® Systems Enzyme Validator Set

3.2 **Classification Name**

Calibrator (21 CFR §862.1150)

4.0 **Predicate Device(s):**

SYNCHRON Systems Reagent	Predicate	Manufacturer	Docket Number
SYNCHRON® Systems Enzyme Validator Set	SYNCHRON® Systems Enzyme Validator Set	Beckman Coulter, Inc.	K971333 K951964

5.0 **Description:**

The SYNCHRON® Systems Enzyme Validator Set Levels 1 and 2 are used for calibration of various enzymes in the clinical laboratory. This consists of 3 X 5 mL bottles each of Levels 1 and 2. The storage temperature for this product is -15°C to -20°C.

5.0 **Intended Use:**

The SYNCHRON Enzyme Validator Set, in conjunction with specified enzyme assays on Beckman SYNCHRON Systems, is intended to provide points of reference in the measurement of selected human enzymes. Use of this product will result in assay values which are compatible with those from methods recommended by the International Federation of Clinical Chemistry (IFCC) and the German Society for Clinical Chemistry (Deutsche Gesellschaft fur Klinische Chemie (DGKCh). Lipase values for specific for the LIP chemistry on SYNCHRON Systems.

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

Identical to predicate product with values assigned to the lipase analyte.

8.0 **Summary of Performance Data:**

The data in the Premarket Notification on safety and effectiveness supports a finding of substantial equivalence to calibrators already in commercial distribution. Stress stability studies of the Enzyme Validator support the Beckman stability claim of 18 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

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

DEC 23 1998

Lucinda Stockert
Staff Regulatory Specialist, Product Submissions
BECKMAN COULTER, INC.
200 S. Kraemer Blvd., W-104
Brea, CA 92822-8000

Re: K984014
Trade Name: SYNCHRON® Systems Enzyme Validator Set
Regulatory Class: II
Product Code: JIX
Dated: November 4, 1998
Received: November 11, 1998

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"(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): ~~Not yet assigned~~ K984014

Device Name: **SYNCHRON® Systems Enzyme Validator Set Levels 1 and 2**

Indications for Use:

The SYNCHRON® Systems Enzyme Validator Set, in conjunction with specified enzyme assays on Beckman SYNCHRON Systems, is intended to provide points of reference in the measurement of selected human enzymes. Use of this product will result in assay values which are compatible with those from methods recommended by the International Federation of Clinical Chemistry (IFCC) and the German Society for Clinical Chemistry (Deutsche Gesellschaft fur Klinische Chemie (DGKCh). Lipase values for specific for the LIP chemistry on SYNCHRON 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.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

for (Division Sign-Off)
Division of Clinical Laboratory Devices
510(k) Number K984014

Prescription Use ✓ OR Over-the-Counter Use _____
(per 21 CFR 801.109)