NOV 26 1999

K993023

BECKMAN COULTER

Summary of Safety and Effectiveness
SYNCHRON® Systems
OP 300 Low and High Urine Controls

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
FAX: (714) 961-4123

2.0 **Date Submitted:**

September 7, 1999

3.0 **Device Name(s):**

3.1 **Proprietary Names**

SYNCHRON® Systems OP 300 Low and High Urine Controls

3.2 **Classification Name**

Clinical Toxicology Control (21 CFR § 862.3280)

4.0 **Predicate Device(s):**

SYNCHRON Systems Reagent	Predicate	Manufacturer	Docket Number
SYNCHRON® Systems OP 300 Low and High Urine Controls	SYNCHRON® Systems DAT Low and High Urine Controls II	Beckman Coulter, Inc.	K983748

5.0 **Description:**

The SYNCHRON® Systems OP 300 Low and High Urine Controls are intended for use on SYNCHRON Systems for the quality control of Opiate 300 ng. This product contains a 5.0 mL bottle of the Low Urine Control and a 5.0 mL bottle of the High Urine Control. The storage temperature for the calibrators is +2°C to +8°C.

6.0 Intended Use:

The Beckman Coulter OP 300 Low and High Urine Controls, in conjunction with SYNCHRON Reagents, are intended for use on SYNCHRON Systems for monitoring the quality control for OP 300 ng in the clinical laboratory.

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

The opiate level between the two products is identical. Both the candidate and the predicate are human, urine-based, ready-to-use liquid calibrators with 300 ng and 1000 ng opiate (morphine) analyte added.

8.0 **Summary of Performance Data:**

The data in the Premarket Notification on safety and effectiveness supports a finding of substantial equivalence to toxicology controls already in commercial distribution. Stress stability studies of the OP 300 Low and High Urine Controls 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

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, W-104
Box 8000
Brea, California 92822-8000

Re: K993023
Trade Name: SYNCHRON® Systems OP 300 Low and High Urine Controls
Regulatory Class: I
Product Code: JJY
Dated: September 7, 1999
Received: September 9, 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 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): K993023

Device Name: **SYNCHRON® Systems OP 300 Low and High Urine Controls**

Indications for Use:

The Beckman Coulter OP 300 Low and High Urine Controls, in conjunction with SYNCHRON Reagents, are intended for use on SYNCHRON Systems for monitoring the quality control for Opiate 300 ng in the clinical laboratory.

Clinical Significance:
The SYNCHRON® Systems OP Low and High Urine Controls are ready-to-use human, urine-based, liquid controls. They are derived by adding known quantities (traceable to Gas Chromatography/Mass Spectrometry) of morphine (for opiate) to human urine to achieve each drug analyte concentration.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Peter E. Maglini

(Division Sign-Off)
Division of Clinical Laboratory Devices K993023
510(k) Number _____

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