K984152

JAN 29 1999

BECKMAN COULTER

Summary of Safety & Effectiveness
SYNCHRON® Systems
Opiates 2000 ng (OP2) Reagent

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:**

November 17, 1998

3.0 **Device Name(s):**

3.1 **Proprietary Names**

SYNCHRON® Systems Opiates 2000 ng Reagent

3.2 **Classification Name**

Opiate Test System (21 CFR §862.3650)

4.0 **Predicate Device(s):**

SYNCHRON Systems Reagent	Predicate	Manufacturer	Docket Number
SYNCHRON® Systems Opiate 2000 ng Reagent	Emit® II Opiates 300/2000 Assay	Behring Diagnostics, Inc.*	K971596

*Behring Diagnostics, Inc. (formerly SYVA), Cupertino, CA

5.0 **Description:**

The SYNCHRON® Systems DAT Opiates Reagent is in a ready-to-use liquid format and packaged into bar coded cartridges that are placed directly onto the SYNCHRON Systems.

5.0 **Intended Use:**

The SYNCHRON Systems Opiates 2000 ng (OP2) Reagent, in conjunction with the SYNCHRON System Drugs of Abuse (DAT) Urine Calibrators, is intended for use in the qualitative determination of Opiates in human urine at a cutoff value of 2000 ng/mL, on SYNCHRON Systems.

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

Same intended use and chemical reaction as the predicate. The SYNCHRON Opiates 2000 ng Reagent uses mouse antibodies and the Emit II Opiates Reagent uses goat antibodies.

8.0 **Summary of Performance Data:**

The data in the Premarket Notification on safety and effectiveness supports a finding of substantial equivalence to Opiate Test Systems already in commercial distribution. Stress stability studies of the Opiates 2000 ng Reagent support the Beckman stability claim of 12 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

JAN 29 1999

Lucinda Stockert
Staff Regulatory Specialist
Beckman Coulter, Inc.
200 S. Kraemer Blvd., W-104
P.O. Box 8000
Brea, CA 92622-8000

Re: K984152
Trade Name: SYNCHRON® Systems Opiates 2000 ng (OP2) Reagent
Regulatory Class: II
Product Code: DJG
Dated: January 14, 1999
Received: January 19, 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.

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): Not yet assigned

Device Name: **SYNCHRON® Systems Opiates 2000 ng Reagent**

Indications for Use:

The SYNCHRON® Systems Opiates 2000 ng (OP2) Reagent, in conjunction with the SYNCHRON System Drugs of Abuse (DAT) Urine Calibrators, is intended for use in the qualitative determination of Opiates in human urine at a cutoff value of 2000 ng/mL, on SYNCHRON Systems.

21 CFR 862.3650 Opiates Test System

(a) *Identification.* An Opiate test system is a device intended to measure any of the addictive narcotic pain relieving opiate drugs in blood, serum, urine, gastric contents, and saliva. An opiate is any natural or synthetic drug that has morphine-like pharmocological actions. The opiates include drugs such as morphine, morphine glucoronide, heroin, codeine, nalorphine, and meperedine. Measurements obtained by this device are used in the diagnosis and treatment of opiate use or overdose and monitoring the levels of opiate administration to ensure appropriate therapy.

(b) *Classification.* Class II.

Jean Cooper
(Division Sign-Off)
Division of Clinical Laboratory Devices
510(k) Number K984152

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(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)