K973069

Summary of Safety & Effectiveness
Beckman SYNCHRON Systems Methadone Reagent

1.0 Submitted By:

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2.0 Date Submitted:

14 August 1997

3.0 Device Name(s):

3.1 Proprietary Names

SYNCHRON® Systems Methadone Reagent

3.2 Classification Name

Methadone Test System (21 CFR § 862.3620)

4.0 Predicate Device(s):

BECKMAN Reagent	Predicate	Predicate Company	Docket Number
SYNCHRON Systems Methadone	SYNCHRON Systems Methadone	Beckman Instruments, Inc.	K944074

5.0 Description:

The SYNCHRON Methadone Reagent, in conjunction with the SYNCHRON CX Drugs of Abuse Testing Urine Calibrators, is intended for the qualitative determination of methadone in human urine, at a cutoff value of 300 ng/mL, on SYNCHRON Systems.

6.0 Intended Use:

The Beckman Methadone assay provides a rapid screening procedure for determining the presence of methadone in urine. The test provides only a preliminary analytical result; a positive result by this assay should be confirmed by another generally accepted non-immunological method such as thin layer chromatography (TLC), gas chromatography (GC), or gas chromatograph/mass spectrometry (GC/MS). GC/MS is the preferred confirmatory method. Clinical Consideration and professional judgment should be applied to any drug of abuse test result, particularly when preliminary positive results are used.

7.0 Comparison to Predicate(s):

The following tables show similarities and differences between the predicate identified in Section 4.0 of this summary.

SIMILARITIES to the PREDICATE

Reagent	Aspect/Characteristic	Comments
SYNCHRON Systems Methadone (METD) Reagent	Intended use	Same as the predicate
	Chemical Reaction	Same principle as the predicate
	Calibration	Same as the predicate
	Reagent Kit Configuration	Same as the predicate
	Product Part Number	Same as the predicate

DIFFERENCES from the PREDICATE

Reagent	Aspect/Characteristic	Comments
SYNCHRON Systems Methadone (METD) Reagent	Specificity of monoclonal antibody	Current Formulation: Specific to both methadone and LAMM New Formulation: Specific only to methadone

8.0 Summary of Performance Data:

The data in the Premarket Notification on safety and effectiveness supports a finding of substantial equivalence of the new SYNCHRON Methadone formulation vs the current formulation. Stress stability studies of the Methadone reagent support the Beckman stability claim of 12 months at 4°C and 60 days on a SYNCHRON instrument.

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

SEP 22 1997

Ms. Lucinda Stockert
Senior Regulatory Specialist
Beckman Instruments, Inc.
200 S. Kraemer Blvd., W-337
Brea, CA 92622-8000

Re: K973069/S1
SYNCHRON® Systems Methadone Reagent
Regulatory Class: II
Product Code: DJR
Dated: September 8, 1997
Received: September 10, 1997

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 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/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 Methadone Reagent**

Indications for Use:

The Beckman SYNCHRON Systems Methadone Reagent, in conjunction with the SYNCHRON Drugs of Abuse Testing Urine Calibrators, is intended for the qualitative determination of methadone in human urine, at a cutoff value of 300 ng/mL, on SYNCHRON Systems.

21 CFR 862.3620 Methadone Test System

(a) *Identification.* A methadone test system is a device intended to measure methadone, an addictive narcotic pain relieving drug, in serum and urine. Measurements obtained by this device are used in the diagnosis and treatment of methadone use or overdose and to determine compliance with regulations in methadone maintenance treatment.

(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)

Carol Benson for Alfred Montgomery

(Division Sign-Off)
Division of Clinical Laboratory Devices
510(k) Number K973069

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