K031002

APR 2 9 2003

510(k) SUMMARY

1.0 Submitted By:

Kim Walker
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Beckman Coulter, Inc.
200 S. Kraemer Blvd. W-104
Brea, CA 92822-8000
Telephone: (714) 961-4912
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2.0 Date Submitted

March 25, 2003

3.0 Device Name(s):

3.1 Proprietary Names
SYNCHRON Systems Opiate Reagent

3.2 Classification Names
Opiate test system. [862.3650]

4.0 Legally Marketed Device

The SYNCHRON Systems Opiate Reagent claims substantial equivalence to the SYNCHRON Systems Opiate Reagent currently in commercial distribution. (FDA 510(k) Number K944606)

5.0 Device Description

The SYNCHRON Systems Opiate (OP) reagent is designed for optimal performance on the SYNCHRON CX (CX4/4CE/4Δ/4PRO, CX5/5CE/5Δ/5PRO, CX7/7RTS/7Δ/7PRO, CX9ALX/9PRO) and LX (LX20/PRO/LXi) Systems. The reagent kit contains one 250-test cartridge that is packaged separately from the associated calibrators.

6.0 Intended Use

Opiate 300 ng (OP) Reagent, in conjunction with the SYNCHRON® System OP 300 Urine Calibrators, is intended for the qualitative determination of opiates in human urine, at a cutoff value of 300 ng/mL (morphine), on SYNCHRON Systems.

The Opiate assay provides a rapid screening procedure for determining the presence of opiates in urine. This 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 chromatography/mass spectrometry (GC/MS). GC/MS is the preferred confirmatory method.[1,2]

Clinical consideration and professional judgement should be applied to any drug of abuse test result, particularly when preliminary positive results are used.

7.0 Comparison to the Predicate (Description of the Modification to the Legally Marketed Device)

The SYNCHRON Systems Opiate reagent antibody has been modified for drug cross-reactivity.

8.0 Summary of Performance Data

Performance data from validation testing supports equivalency.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

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Ms. Kim Walker
Senior Regulatory Affairs Specialist
Beckman Coulter, Inc.
200 S. Kraemer Boulevard
M/S W-104, Box 8000
Brea, CA 92822-8000

Re: k031002
Trade/Device Name: SYNCHRON® Systems Opiate Reagent
Regulation Number: 21 CFR 862.3650
Regulation Name: Opiate Test System
Regulatory Class: Class II
Product Code: DJG
Dated: March 25, 2003
Received: March 31, 2003

Dear Ms. Walker:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and 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) that do not require approval of a premarket approval application (PMA). 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 (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820).

This letter will allow you to begin marketing your device as described in your Section 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 information about the application of labeling requirements to your device, or questions on the promotion and advertising of your device, please contact the Office of In Vitro Diagnostic Device Evaluation and Safety at (301) 594-3084. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer 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
Office of *In Vitro* Diagnostic Device
Evaluation and Safety
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known):

Device Name: **SYNCHRON® Systems Opiate Reagent**

Indications for Use:

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The Opiate assay provides a rapid screening procedure for determining the presence of opiates in urine. This 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 chromatography/mass spectrometry (GC/MS). GC/MS is the preferred confirmatory method.[1,2]

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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) Optional Format 1-2-96

Dean Cooper
(Division Sign-Off)
Division of Clinical Laboratory Devices
510(k) Number K031002