K023048

NOV 7 2002

510(k) SUMMARY

1.0 Submitted By:

Annette Hellie
Regulatory Affairs Manager
Beckman Coulter, Inc.
200 S. Kraemer Blvd. W-104
Brea, CA 92822-8000
Telephone: (714) 993-8767
FAX: (714) 961-4123

2.0 Date Submitted

September 12, 2002

3.0 Device Name(s):

3.1 Proprietary Names
SYNCHRON Systems Benzodiazepine Reagent

3.2 Classification Names
Benzodiazepine test system. [862.3170]

4.0 Legally Marketed Device

The SYNCHRON Systems Benzodiazepine Reagent claims substantial equivalence to the SYNCHRON Systems Benzodiazepine Reagent currently in commercial distribution. (FDA 510(k) Number K944076)

5.0 Device Description

The SYNCHRON Systems Benzodiazepine (BENZ) 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) Systems. The reagent kit contains one 250-test cartridge that is packaged separately from the associated calibrators.

6.0 Intended Use

Benzodiazepine (BENZ) Reagent, in conjunction with SYNCHRON ® Systems Drugs of Abuse Testing (DAT) Urine Calibrators, is intended for the qualitative determination of benzodiazepines in human urine at a cutoff value of 200 ng/mL, on SYNCHRON Systems.

The Benzodiazepine assay provides a rapid screening procedure for determining the presence of benzodiazepines 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.

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

The SYNCHRON Systems Benzodiazepine 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

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

NOV 7 2002

Ms. Annette Hellie
Regulatory Affairs Manager
Beckman Coulter, Inc.
200 S. Kraemer Blvd. W-104
P.O. Box 8000
Brea, CA 92822-8000

Re: k023048
Trade/Device Name: Synchron® Systems Benzodiazepine Reagent
Regulation Number: 21 CFR 862.3170
Regulation Name: Antimony test system
Regulatory Class: Class II
Product Code: JXM
Dated: October 24, 2002
Received: October 24, 2002

Dear Ms. Hellie:

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 the Code of Federal Regulations, Title 21, Parts 800 to 898. 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 Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

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" (21CFR 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
Division of Clinical Laboratory-Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

page 1 of 1

510(k) Number (if known): K023048

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

Indications for Use:

Benzodiazepine (BENZ) Reagent, in conjunction with SYNCHRON ® Systems Drugs of Abuse Testing (DAT) Urine Calibrators, is intended for the qualitative determination of benzodiazepines in human urine at a cutoff value of 200 ng/mL, on SYNCHRON Systems.

The Benzodiazepine assay provides a rapid screening procedure for determining the presence of benzodiazepines 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.

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

(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

(Division Sign-Off)
Division of Clinical Laboratory Devices
510(k) Number K023048