K 043556

MAR 2 8 2005

510(k) Summary
SYNCHRON® Systems BNZG Reagent

1.0 **Submitted By:**

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2.0 **Date Submitted:**

December 22, 2004

3.0 **Device Name(s):**

3.1 **Proprietary Names**

SYNCHRON® Systems Benzodiazepines (BNZG) Reagent

3.2 **Classification Name**

Benzodiazepine test system [21 CFR § 862.3170]

4.0 **Predicate Device:**

Candidate(s)	Predicate	Manufacturer	Docket Number
SYNCHRON Systems BNZG Reagent	SYNCHRON Systems BENZ Reagent	Beckman Coulter, Inc.	K023048

5.0 **Description:**

The BNZG assay provides a rapid screening procedure for determining the presence of the analyte in urine. This test provides only a preliminary analytical result; a positive result by these assays 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.

6.0 **Intended Use:**

BNZG reagent, when used in conjunction with SYNCHRON® System(s) and SYNCHRON® Systems Drugs of Abuse Testing (DAT) Urine Calibrators, is intended for the qualitative determination of Benzodiazepine (BNZG) in human urine at a cutoff value of 200 ng/mL (oxazepam).

The BNZG assay provides a rapid screening procedure for determining the presence of the analyte in urine. This test provides only a preliminary analytical result; a positive result by these assays 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.

Clinical Significance:

Benzodiazepines are a class of central nervous system depressants that are used as sedatives and hypnotics. The benzodiazepine compounds include chlordiazepoxide, diazepam, oxazepam, flurazepam, and nitrazepam. Measurements of benzodiazepines on the SYNCHRON System(s) are used in the diagnosis and treatment of benzodiazepine use and overdose, and in monitoring the presence of benzodiazepines to ensure appropriate therapy.

7.0 Comparison to Predicate(s):

The following table shows similarities and differences between the predicates identified in Section 4.0 of this summary.

	Similarities	
BNZG Reagent	Intended Use	Same as BENZ
	Liquid stable reagent	
	Stability	
	Calibrators	
	Controls	
	Differences	
BNZG Reagent	Cross reactivity	Different due to new antibody and glucuronidase enzyme
	Reagent volume	260 µL for BNZG due to enzyme 250 µL for BENZ

8.0 Summary of Performance Data:

The data in the Premarket Notification on safety and effectiveness supports a finding of substantial equivalence to chemistry test systems already in commercial distribution. Equivalence is demonstrated through method comparison, stability, linearity, and imprecision experiments.

BNZG Concordance Summary
SYNCHRON CX Systems

		SYNCHRON CX BNZG		
		POS	NEG	TOTAL
GC/MS	POS	93	2	95
	NEG	10	53	63
	TOTAL	103	55	158

Sensitivity	98%
Specificity	84%
Overall Agreement	92%

BNZG Concordance Summary
SYNCHRON LX Systems

		SYNCHRON LX20 BNZG		
		POS	NEG	TOTAL
GC/MS	POS	93	2	95
	NEG	10	53	63
	TOTAL	103	55	158

Sensitivity	98%
Specificity	84%
Overall Agreement	92%

SYNCHRON CX System BNZG Reagent Imprecision Results

Sample	Mean Rate (mA/min)	S.D.	%C.V.	N
Within-Run Imprecision				
Urine Control 1	408.95	2.129	0.5	80
Urine Control 2	447.26	3.431	0.8	80
Urine Pool	438.91	3.407	0.8	80
Total Imprecision				
Urine Control 1	408.95	2.931	0.7	80
Urine Control 2	447.26	4.258	1.0	80
Urine Pool	438.91	3.883	0.9	80

SYNCHRON LX System BNZG Reagent Imprecision Results

Sample	Mean Rate (mA/min)	S.D.	%C.V.	N
Within-Run Imprecision				
Urine Control 1	439.00	3.276	0.8	80
Urine Control 2	480.04	4.631	1.0	80
Urine Pool	470.16	4.133	0.9	80
Total Imprecision				
Urine Control 1	439.00	4.524	1.0	80
Urine Control 2	480.04	4.839	1.0	80
Urine Pool	470.16	4.905	1.0	80

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

MAR 2 8 2005

Ms. Annette Hellie
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Re: k043556
Trade/Device Name: SYNCHRON® Systems Benzodiazepines (BNZG) Reagent
Regulation Number: 21 CFR 862.3170
Regulation Name: Benzodiazepines test system
Regulatory Class: Class II
Product Code: JXM
Dated: March 4, 2005
Received: March 15, 2005

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 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 (240)276-0484. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act 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/industry/support/index.html

Sincerely yours,

Jean M. Cooper MS, DVM

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Director
Division of Chemistry and Toxicology
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Enclosure