K971506

JUN - 3 1997

Summary of Safety & Effectiveness
SYNCHRON® Systems Alcohol (ALC) Reagent

1.0 Submitted By:

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2.0 Date Submitted:

18 April 1997

3.0 Device Name(s):

3.1 Proprietary Names

SYNCHRON® Systems Alcohol (ALC) Reagent

3.2 Classification Names

Alcohol Test system (21 CFR 862.3040)

4.0 Predicate Device(s):

SYNCHRON Reagent	Predicate	Predicate Company	Docket Number
SYNCHRON Systems Alcohol (ALC) Reagent	DCL Ethanol Assay	Diagnostic Chemicals Limited (DCL), Charlottetown, PEI, Canada	K923783 K924733

5.0 Description:

The SYNCHRON Systems Alcohol (ALC) Reagent in conjunction with SYNCHRON Systems Alcohol Calibrator, is intended for use on Beckman's SYNCHRON Systems Clinical Systems.

6.0 Intended Use:

The SYNCHRON Systems Alcohol (ALC) Reagent, when used in conjunction with SYNCHRON Systems Alcohol Calibrator, is intended for the quantitative determination of alcohol in human serum or plasma. This assay is designed for use with clinical chemistry analyzers from Beckman Instruments, such as the SYNCHRON LX™20 Clinical System.

7.0 Comparison to Predicate(s):

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

Reagent	Aspect/ Characteristic	Comments
SIMILARITIES		
SYNCHRON Systems Alcohol (ALC) Reagent	Intended use	Same as DCL Ethanol Assay Kit; determination of alcohol concentration in serum or plasma
	Chemical reaction	Same as DCL Ethanol Assay Kit; enzymatic, Alcohol Dehydrogenase (ADH) reaction
	Formulation	Same as DCL Ethanol Assay Kit
	Measurement method	Same as DCL Ethanol Assay Kit; endpoint measurement at 340 nm
	Packaging	Same as DCL Ethanol Assay Kit; a multi reagent kit that requires preparation.
	Calibration	Same as DCL Ethanol Assay Kit; single level aqueous calibrator

Reagent	Aspect/ Characteristic	Comments
DIFFERENCES		
SYNCHRON Systems Alcohol (ALC) Reagent	Range expansion	The DCL Ethanol Assay Kit measures alcohol concentrations at the initial range of 5 -250 mg/dL; while the SYNCHRON Systems ALC reagent measures alcohol concentrations at the initial range of 5 - 250 mg/dL and expanded range of 200 - 500 mg/dL

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 studies and imprecision experiments that relate results obtained from SYNCHRON Systems Alcohol Reagent.

Method Comparison Study Results
SYNCHRON Systems Alcohol (ALC) Reagent

Reagent (Analyte)	Slope	Intercept (mg/dL)	r	n	Predicate Method
SYNCHRON Systems Alcohol (ALC) Reagent	1.037	0.34	0.9986	78	DCL Ethanol Assay Kit on the SYNCHRON CX Systems

Estimated Within-Run Imprecision Alcohol Reagent

Sample	Mean (mg/dL)	S.D. (mg/dL)	%C.V.	N
Within-Run Imprecision Default Range				
Level 1	51.4	0.89	1.73	80
Level 2	102.2	1.57	1.53	80
Level 3	239.7	3.19	1.33	80
Within-Run Imprecision Extended Range				
Level 1	287.55	3.58	1.24	20
Level 2	488.63	6.08	1.24	20

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

JUN - 3 1997

Sheri Hall
Manager, Premarket Regulatory
Beckman Instruments, Inc.
200 S. Kraemer Boulevard, M/S W-337
P.O. Box 8000
Brea, California 92822-8000

Re: K971506
SYNCHRON® Systems Alcohol (ALC) Reagent
Regulatory Class: II
Product Code: DIC, DMT
Dated: April 18, 1997
Received: April 25, 1997

Dear Ms. Hall:

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 Good Manufacturing Practice for Medical Devices: General (GMP) regulation (21 CFR Part 820) and that, through periodic GMP 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):

Device Name: **SYNCHRON® Systems Alcohol (ALC) Reagent**

Indications for Use:

The SYNCHRON Systems Alcohol (ALC) Reagent, when used in conjunction with SYNCHRON Systems Alcohol Calibrator, is intended for the quantitative determination of alcohol in human serum or plasma samples. This assay is designed for use with clinical chemistry analyzers from Beckman instruments, such as the SYNCHRON LX20 Clinical System.

21 CFR 862.3040 Alcohol test system

(a) *Identification.* **An alcohol test system is a device intended to measure alcohol (e.g., ethanol, methanol, isopropanol, etc.) in human body fluids (e.g., serum, whole blood, and urine). Measurements obtained by this device are used in the diagnosis and treatment of alcohol intoxication and poisoning.**

(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)

(Division Sign-Off)
Division of Clinical Laboratory Devices
510(k) Number K041306

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