OCT 14 1998

K982935

BECKMAN COULTER

Summary of Safety & Effectiveness
SYNCHRON® Systems Digoxin (DIGN) Reagent

1.0 **Submitted By:**

Lucinda Stockert
Staff Regulatory Specialist, Product Submissions
Beckman Coulter, Inc.
200 S. Kraemer Blvd., W-104
Brea, California 92822-8000
Telephone: (714) 961-3777
FAX: (714) 961-4123

2.0 **Date Submitted:**

August 19, 1998

3.0 **Device Name(s):**

3.1 **Proprietary Names**

SYNCHRON® Systems Digoxin (DIGN) Reagent
SYNCHRON® Systems Drug Calibrator 2

3.2 **Classification Name**

Digoxin (21CFR §862.3320)
Calibrator (21 CFR §862.3200)

4.0 **Predicate Device(s):**

SYNCHRON Systems Reagent	Predicate	Manufacturer	Docket Number
SYNCHRON® Systems Digoxin (DIGN)	TDx®** Digoxin II	Abbott* Laboratories, Inc	K882233

*Abbott Laboratories, Abbott Park, IL 60064
**Trademark of Abbott Laboratories

5.0 **Description:**

The SYNCHRON System Digoxin (DIGN) Reagent is designed for optimal performance on the SYNCHRON CX and LX Systems. It is intended for use in the quantitative determination of Digoxin in human serum or plasma.

6.0 Intended Use:

The SYNCHRON® Systems Digoxin (DIG) Reagent, when used in conjunction with Beckman SYNCHRON® Systems and SYNCHRON® Systems Drug Calibrator 2 set, is intended for the quantitative determination of total digoxin in human serum or plasma on SYNCHRON® Systems.

The SYNCHRON® Systems Drug Calibrator 2, used in conjunction with SYNCHRON® Digoxin reagent, is intended for use on Beckman's SYNCHRON Systems for the calibration of Digoxin test systems.

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	
SYNCHRON® Systems Digoxin (DIGN)	Intended use.	Same as Abbott TDx Digoxin II Reagent
	Liquid stable reagents.	
	Multipoint Calibration Scheme	
	Reagent measures digoxin in both human plasma and serum samples	
	DIFFERENCES	
SYNCHRON® Systems Digoxin (DIGN)	SYNCHRON DIGN utilizes turbidimetric inhibition immunoassay	Abbott TDx Digoxin reagent utilizes fluorescence polarization immunoassay
	Antibody source for SYNCHRON DIGN is mouse.	Antisera source for TDx Digoxin II is rabbit.
	Sample Pretreatment	SYNCHRON Systems DIGN does not require sample pretreatment while the predicate requires sample pretreatment

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, and imprecision experiments.

Method Comparison Study Results
SYNCHRON® Systems Digoxin (DIGN) Reagent

SYNCHRON DIGN Reagent	Sample Type	Slope	Intercept (ng/mL)	r	n	Predicate Method
SYNCHRON CX System	serum	1.053	-0.03	0.991	113	Abbott TDx Digoxin II
SYNCHRON LX System	serum	1.054	-0.06	0.990	112	Abbott TDx Digoxin II

Estimated Within-Run Imprecision

SYNCHRON System	Sample	Mean (ng/mL)	S.D. (ng/mL)	%C.V.	N
CX	Level 1	0.74	0.05	6.96	80
	Level 2	1.73	0.06	3.29	80
	Level 3	2.48	0.05	1.80	80
LX	Level 1	0.80	0.05	6.06	80
	Level 2	1.78	0.03	1.78	80
	Level 3	2.49	0.07	2.62	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

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

OCT 14 1998

Lucinda Stockert
Staff Regulatory Specialist
Beckman Coulter, Inc.
200 S. Kraemer Boulevard, M/S W-104
P.O. Box 8000
Brea, California 92822-8000

Re: K982935
SYNCHRON® Systems Digoxin Reagent
Regulatory Class: II
Product Code: KXT, DLJ
Dated: August 19, 1998
Received: August 21, 1998

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): K 982935

Device Name: **SYNCHRON® Systems**
Digoxin (DIGN) Reagent

Indications for Use:

The SYNCHRON® Systems Digoxin (DIGN) Reagent, when used in conjunction with Beckman SYNCHRON® Systems and SYNCHRON® Systems Drug Calibrator 2 set, is intended for the quantitative determination of total digoxin in human serum or plasma on SYNCHRON® Systems.

The SYNCHRON® Systems Drug Calibrator 2, used in conjunction with SYNCHRON® Digoxin reagent, is intended for use on Beckman's SYNCHRON Systems for the calibration of Digoxin test systems.

Clinical Significance:

Digoxin is administered for conditions of heart failure or in the treatment of certain cardiac arrhythmias. Digoxin therapy is monitored for possible toxicity and inadequate therapeutic response.

(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 K982935

Prescription Use ✓ OR Over-the-Counter Use ____
(per 21 CFR 801.109) Optional Format 1-2-96