

K971505

June 11, 1997

Summary of Safety & Effectiveness
SYNCHRON® Systems Cholesterol (CHOL) Reagent

1.0 **Submitted By:**

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Beckman Instruments, Inc.
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2.0 **Date Submitted:**

18 April 1997

3.0 **Device Name(s):**

3.1 **Proprietary Names**

SYNCHRON® Systems Cholesterol (CHOL) Reagent

3.2 **Classification Names**

Cholesterol (Total) Test system (21 CFR 862.1175)

4.0 Predicate Device(s):

SYNCHRON Reagent	Predicate	Predicate Company	Docket Number
SYNCHRON Systems Cholesterol (CHOL) Reagent	SYNCHRON CX Systems Cholesterol (CHOL) Reagent	Beckman Instruments, Inc.	K934046
SYNCHRON CX4/CX5 Systems	ASTRA & SYNCHRON CX3	Beckman Instruments, Inc	K881498 K881495
SYNCHRON CX5CE System	SYNCHRON CX4/CX5 Systems	Beckman Instruments, Inc	K926060
SYNCHRON CX4CE/CX7 System	SYNCHRON CX4/CX5 Systems	Beckman Instruments, Inc	K904220 K904219
SYNCHRON Systems CX4/CX5 Systems	SYNCHRON Systems CX4/CX5 Systems	Beckman Instruments, Inc	K950958
SYNCHRON LX 20 System	SYNCHRON CX7 DELTA System	Beckman Instruments, Inc.	K965240

5.0 Description:

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

6.0 Intended Use:

The SYNCHRON Systems Cholesterol (CHOL) Reagent, when used in conjunction with SYNCHRON Systems Multi Calibrator, is intended for the quantitative determination of human cholesterol in 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 Cholesterol (CHOL) Reagent	Intended use	Same; determination of cholesterol concentration in serum or plasma
	Chemical reaction	Same; enzymatic, Cholesterol Oxidase reaction
	Measurement method	Same; endpoint measurement at 520 nm
	Packaging	Same; a two cartridge reagent kit
	Reaction time	Same; 32 seconds
	Calibration	Same; single level serum base calibrator

Reagent	Aspect/ Characteristic	Comments
DIFFERENCES		
SYNCHRON Systems Cholesterol (CHOL) Reagent	Range expansion	The SYNCHRON CX Systems measures cholesterol concentrations at the initial range of 5 -750 mg/dL; while the SYNCHRON LX Systems measures cholesterol concentrations at the initial range of 5-750 mg/dL and expanded range of 600 - 1000 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 Cholesterol Reagent.

Method Comparison Study Results
 SYNCHRON Systems Cholesterol (CHOL) Reagent

Reagent (Analyte)	Slope	Intercept (mg/dL)	r	n	Predicate Method
SYNCHRON Systems Cholesterol (CHOL) Reagent	0.983	2.41	0.9996	79	SYNCHRON Systems Cholesterol (CHOL) Reagent
SYNCHRON Systems Cholesterol (CHOL) Reagent	1.002	-2.07	0.9961	39	Abell-Kendall Reference Method

Estimated Within-Run Imprecision Cholesterol Reagent

Sample	Mean (mg/dL)	S.D. (mg/dL)	%C.V.	N
Within-Run Imprecision Default Range				
Level 1	98.7	1.08	1.09	80
Level 2	155.4	1.65	1.06	80
Level 3	213.2	20.8	0.98	80
Within-Run Imprecision Extended Range				
Level 1	716.2	12.53	2.28	20
Level 2	876.25	19.94	1.74	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.



Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

JUN 11 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

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Re: K971505
SYNCHRON® Systems Cholesterol (CHOL) Reagent
Regulatory Class: I
Product Code: CHH
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.

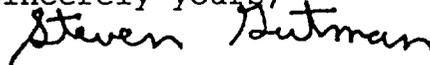
Page 2

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 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 Cholesterol (CHOL) Reagent

Indications for Use:

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

21 CFR 862.1175 Cholesterol (total) test system

(a) Identification. A cholesterol (total) test system is a device intended to measure cholesterol in plasma and serum. Cholesterol measurements are used in the diagnosis and treatment of disorder involving excess cholesterol in the blood and lipid and lipoprotein metabolism disorders.

(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 159771505

Prescription Use [checked]
(per 21 CFR 801.109)

OR

Over-the-Counter Use
Optional Format 1-2-96