SEP 16 2004

K042195

510(k) Summary
SYNCHRON® Systems
HDL Cholesterol Reagent and Lipid Plus Calibrators 1 & 2

1.0 **Submitted By:**

Kim Walker
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200 S. Kraemer Blvd., W-104
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2.0 **Date Submitted:**

August 11, 2004

3.0 **Device Name(s):**

3.1 **Proprietary Names**

SYNCHRON® Systems HDL Cholesterol (HDL) Reagent
SYNCHRON® Systems Lipid Plus Calibrators 1 & 2

3.2 **Classification Name**

Lipoprotein test system (21 CFR § 862.1475)
Calibrator, Primary (21 CFR § 862.1150)

4.0 **Predicate Devices:**

Candidate(s)	Predicate	Manufacturer	Docket Number
SYNCHRON Systems HDL Reagent	SYNCHRON Systems HDLD Reagent	Beckman Coulter, Inc.	K040767
SYNCHRON® Systems Lipid Plus Calibrators 1 & 2	SYNCHRON® Systems Lipid Calibrator	Beckman Coulter, Inc.	K983640

5.0 Description:

Reagent
The SYNCHRON LX® and CX® CE/DELTA/PRO System(s) HDL reagent is designed for optimal performance on the SYNCHRON LX® and CX® CE/DELTA/PRO System(s). The reagent kit contains two 200-test cartridges that are packaged separately from the associated calibrators.

Calibrator
The SYNCHRON® Systems Lipid Plus Calibrator set is a two level ready-to-use human serum-based liquid calibrator set manufactured by Beckman Coulter, Inc. Each kit contains 1 X 3 mL bottles of each level of calibrator (identified as Level 1 and Level 2).

6.0 Intended Use:

Reagent
HDL reagent, when used in conjunction with SYNCHRON LX® System(s) and SYNCHRON® Systems Lipid Plus Calibrator, is intended for the quantitative determination of HDL Cholesterol (HDL) in the high density lipoprotein (HDL) fraction of human serum or plasma.

HDL reagent, when used in conjunction with SYNCHRON CX® CE/DELTA/PRO System(s) and SYNCHRON® Systems Lipid Plus Calibrator, is intended for the quantitative determination of HDL Cholesterol (HDL) in the high density lipoprotein (HDL) fraction of human serum or plasma.

Calibrator
The SYNCHRON Systems Lipid Plus Calibrators 1& 2, in conjunction with specified assays on the SYNCHRON® Systems, are intended to provide points of reference in the measurement of selected human lipids and proteins.

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 to the Predicate

Reagent	Aspect/Characteristic	Comments
HDL Reagent	Intended Use	Same as Beckman SYNCHRON HDLD Reagent
	Liquid Stable Reagent	
	Analytical Range	
	Sample Type	
	Reference Intervals	
	Shelf Life Stability	
Lipid Plus Calibrator	Liquid Stable Calibrator	Same as Beckman SYNCHRON Lipid Calibrator
	Value Assignment Methodology	
	Storage Temperature (-15°C to –20°C)	
	Levels of Analyte (2 levels)	

Differences From The Predicate

Reagent	Aspect/ Characteristic	Comments
HDL Reagent	Sample Size	HDLD is 3 μl, HDL is 4 μl
	Methodology	HDLD uses solubilization polyanion; HDL uses a cholesterol oxidase acceleration and dissolving of HDL by use of a specific detergent.
	Reactive Ingredients	HDL added Ascorbic oxidase, removed the Polyanion and increased the detergent concentration.
	Interferences	HDLD Ascorbic acid 50 mg/dL; HDL 100 mg/dL HDLD IgG 3000 mg/dL; HDL 5000 mg/dL
Lipid Plus Calibrator	Intended Use	The SYNCHRON® Systems Lipid Calibrator is intended for use with the SYNCHRON Systems for the calibration of direct HDL Cholesterol reagent. SYNCHRON Systems Lipid Plus Calibrators 1 & 2 are stabilized liquid calibrators designed for use with SYNCHRON® Systems for the calibration of Lipids and Proteins.
	Shelf Life Stability	Lipid Calibrator is stable up to 18 months; Lipid Plus Calibrator is stable up to 24 months
	Source Material	Lipid Calibrator contains defibrinated human plasma spiked with human lipids; Lipid Plus Calibrator is human serum based and contains endogenous levels of HDL

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.

Method Comparison Study Results

Instrument	Slope	Intercept	r	n	Comparison Method
SYNCHRON CX	0.992	-2.8	0.994	79	SYNCHRON HDLD
SYNCHRON LX	1.000	-2.8	0.993	79	SYNCHRON HDLD

SYNCHRON CX System HDL Reagent Imprecision Results

Sample	Mean (mg/dL)	S.D. (mg/dL)	%C.V.	N
Within-Run Imprecision				
Level 1	28.0	0.5	1.6	80
Level 2	57.6	0.9	1.5	80
Level 3	76.3	2.1	2.8	80
Total Imprecision				
Level 1	28.0	1.4	5.1	80
Level 2	57.6	1.4	2.4	80
Level 3	76.3	2.6	3.4	80

SYNCHRON LX System HDL Reagent Imprecision Results

Sample	Mean (mg/dL)	S.D. (mg/dL)	%C.V.	N
Within-Run Imprecision				
Level 1	27.6	0.3	1.2	80
Level 2	56.0	0.8	1.5	80
Level 3	72.7	1.7	2.3	80
Total Imprecision				
Level 1	27.6	1.7	6.1	80
Level 2	56.0	1.6	2.9	80
Level 3	72.7	1.9	2.6	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

SEP 16 2004

Ms. Kim Walker
Regulatory Affairs Manager
Beckman Coulter, Inc.
200 S. Kraemer Boulevard
P.O. Box 8000
Brea, CA 92822-8000

Re: k042195
Trade/Device Name: SYNCHRON® Systems HDL Cholesterol (HDL) Reagent
SYNCHRON® Systems Lipid Plus Calibrators 1&2
Regulation Number: 21 CFR 862.1150
Regulation Name: Calibrator
Regulatory Class: Class II
Product Code: JIT, LBS
Dated: August 11, 2004
Received: August 13, 2004

Dear Ms. Walker:

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 (301) 594-3084. 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/dsma/dsmamain.html.

Sincerely yours,

Jean M. Cooper MS, DVM.

Jean M. Cooper, MS, D.V.M.
Director
Division of Chemistry and Toxicology
Office of *In Vitro* Diagnostic Device
Evaluation and Safety
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K042195

Device Name: **SYNCHRON® Systems HDL Cholesterol (HDL) Reagent**
SYNCHRON® Systems Lipid Plus Calibrators 1 & 2

Indications for Use:

Reagent:

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HDL reagent, when used in conjunction with SYNCHRON CX® CE/DELTA/PRO System(s) and SYNCHRON® Systems Lipid Plus Calibrator, is intended for the quantitative determination of HDL Cholesterol (HDL) in the high density lipoprotein (HDL) fraction of human serum or plasma.

Calibrator:

The SYNCHRON® Systems Lipid Plus Calibrator 1& 2, in conjunction with specified assays on the SYNCHRON® Systems, are intended to provide points of reference in the measurement of selected human lipids and proteins.

Prescription Use ✓ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

Division Sign-Off

Office of In Vitro Diagnostic Device Evaluation and Safety

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