K100010

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

MAY 14 2010

1.0 **Submitted By:**

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2.0 **Date Submitted:**

December 18, 2009

3.0 **Device Name(s):**

3.1 **Proprietary Names**
SYNCHRON® Systems HDL Cholesterol (HDLX) Reagent

3.2 **Classification Name**

- LDL & VLDL precipitation, Cholesterol via esterase-oxidase, HDL (Product Code – LBS; 21 CFR § 862.1475)

4.0 **Predicate Device:**

Candidate(s)	Predicate	Manufacturer	Docket Number
SYNCHRON® Systems HDL Cholesterol (HDLX) Reagent	Olympus HDL Cholesterol Assay	OLYMPUS AMERICA, INC.	K040692

5.0 **Description:**

HDLX reagent, when used in conjunction with SYNCHRON LX® System(s), UniCel® DxC 800 System(s) and Genzyme Liquid N-geneous® HDL Cholesterol Calibrator is intended for quantitative determination of HDL Cholesterol in the high density lipoprotein fraction of human serum or plasma.

HDL cholesterol measurements are used in the diagnosis and treatment of lipid disorders (such as diabetes mellitus), atherosclerosis, and various liver and renal diseases, and for the assessment of the risk of developing cardiovascular disease.

This direct HDL Cholesterol method is a homogeneous assay without the need for any offline pretreatment or centrifugation steps. The method depends on a unique detergent which solubilizes only the HDL lipoprotein particles and releases HDL cholesterol to react with cholesterol esterase and cholesterol oxidase in the presence of chromogens, to produce a color product. The same detergent also inhibits the reaction of the cholesterol enzymes with LDL, VLDL, and chylomicrons lipoproteins by adsorbing to their surfaces. A polyanion contained in the reagent enhances the selectivity for HDL cholesterol assay by complexing LDL, VLDL, and chylomicrons lipoproteins.

HDLX reagent is used to measure the cholesterol concentration by a timed-endpoint method. The SYNCHRON® System(s) automatically proportions the appropriate HDL cholesterol sample and reagent volumes into a cuvette. The ratio used is one part sample to 93 parts reagent. The System monitors the change in absorbance at 560 nanometers. This change in absorbance is directly proportional to the concentration of cholesterol in the sample and is used by the System to calculate and express the HDL-cholesterol concentration.

6.0 Intended Use:

HDLX reagent, when used in conjunction with SYNCHRON LX® System(s), UniCel® DxC 800 System(s) and Genzyme Liquid N-geneous® HDL Cholesterol Calibrator is intended for quantitative determination of HDL Cholesterol in the high density lipoprotein fraction of human serum or plasma.

Indications for Use:

HDL cholesterol measurements are used in the diagnosis and treatment of lipid disorders (such as diabetes mellitus), atherosclerosis, and various liver and renal diseases, and for the assessment of the risk of developing cardiovascular disease.

7.0 Comparison to Predicate(s):

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

List of design inputs that are similar between the two devices

Predicate Device: Olympus HDL Cholesterol Assay	Current device: SYNCHRON® Systems HDL Cholesterol (HDLX) Reagent
LIQUID stable reagents (ready to use)	same
Intended Use	same
Clinical Significance	same
Fundamental Technology: chromogenic colored change measured by spectrophotometer	same
Sample Types: Serum, Plasma (Heparinized, EDTA)	same
Reference Interval	same

List of design inputs that are different between the two devices

	Predicate Device: Olympus HDL Cholesterol Assay	Current device: SYNCHRON® Systems HDL Cholesterol (HDLX) Reagent
Analytical Range	2.5 – 200 mg/dL	5 - 135 mg/dL
Interfering substances	Hemoglobin: 500 mg/dL Unconjugated Bilirubin: 40 mg/dL Conjugated Bilirubin: 40 mg/dL Lipemia: ≤ 1500 mg/dL (Intralipid) Triglyceride: ≤ 900 mg/dL (triglyceride) Ascorbic Acid: 20 mg/dL Immunoglobulin IgG: 5000 mg/dL	Hemoglobin: 500 mg/dL Bilirubin: 30 mg/dL Lipemia: ≤ 1700 mg/dL (triglyceride) Ascorbic Acid: 50 mg/dL Immunoglobulin IgG: 3000 mg/dL
Sensitivity	Typical change in absorbency for 1 mg/dL of HDL-Cholesterol is 1 mA	5 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, stability, linearity, and imprecision experiments.

Method Comparison Study Results

Candidate	Platform	Slope	Intercept	R	N	Predicate Method
SYNCHRON Systems HDL Cholesterol (HDLX)	UniCel DxC 800	1.06	-4.9	0.991	100	Olympus HDLX Assay (K040692)
SYNCHRON Systems HDL Cholesterol (HDLX)	LX20	1.06	-5.5	0.984	100	Olympus HDLX Assay (K040692)

SYNCHRON® Systems HDL Cholesterol (HDLX) Reagent Precision Study Results

Sample	Mean (mg/dL)	S.D. (mg/dL)	%C.V.	N
Within-Run Imprecision – DxC 800				
SYN 1	31.82	0.53	1.66	20
SYN 2	46.56	0.39	0.85	20
SYN 3	62.33	0.51	0.82	20
Vigil Lipid 1	20.20	0.37	1.83	20
Vigil Lipid 2	57.63	0.65	1.13	20
Vigil Lipid 4	98.75	0.84	0.85	20
Within-Run Imprecision – LX20				
SYN 1	33.13	0.35	1.05	20
SYN 2	47.56	0.37	0.77	20
SYN 3	62.61	0.55	0.87	20
Vigil Lipid 1	23.11	0.38	1.64	20
Vigil Lipid 2	58.94	0.78	1.33	20
Vigil Lipid 4	99.79	1.39	1.39	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 & Drug Administration
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MAY 14 2010

Re: k100010
Trade/Device Name: SYNCHRON® Systems HDL Cholesterol (HDLX) Reagent
Regulation Number: 21 CFR §862.1475
Regulation Name: Lipoprotein Test System
Regulatory Class: Class I; meets limitations of exemptions under 21 CFR § 862.9 (c)(2)
Product Code: LBS
Dated: May 10, 2010
Received: May 11, 2010

Dear Yvette Lloyd:

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); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820).

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of *In Vitro* Diagnostic Device Evaluation and Safety at (301) 796-5450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (301) 796-5760. For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

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) 796-5680 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Courtney C. Harper, Ph.D.
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): k100010

Device Name: SYNCHRON® Systems HDL Cholesterol (HDLX) Reagent

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

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

Concurrence of CDRH, Office of In Vitro Diagnostic Device Evaluation and Safety (OIVD)

Division Sign-Off
Office of In Vitro Diagnostic Device
Evaluation and Safety

510(k) K100010