

Summary of Safety & Effectiveness
SYNCHRON® Systems
Cholinesterase (CHEX) Reagent

K103373
FEB -7 2011

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.

1.0 **Submitted By:**

Yvette Lloyd, JD
Staff Regulatory Affairs Specialist
Beckman Coulter, Inc.
250 S. Kraemer Blvd
Mail Stop: E2.SE.08
Brea, CA 92821
Phone: (714) 961-3626
FAX: (714) 961-4234
email: yrloyd@beckman.com

2.0 **Date Submitted:**

November 16, 2010

3.0 **Device Name(s):**

3.1 **Proprietary Names**

SYNCHRON® Systems Cholinesterase (CHEX) Reagent

3.2 **Classification Name**

Cholinesterase test system, (Product Code – DIH; 21 CFR § 862.3240)

4.0 **Predicate Device:**

Candidate(s)	Predicate	Manufacturer	Docket Number
SYNCHRON® Systems Cholinesterase (CHEX) Reagent	Cholinesterase (CHE)	OLYMPUS AMERICA, INC.	K030045

5.0 **Description:**

System reagent for the quantitative determination of Cholinesterase activity (E.C. 3.1.1.8)1 in human serum and plasma on Beckman Coulter Synchron CX® Pro System(s), Synchron LX® Pro System(s) and UniCel® DxH 600/800 System(s).

A cholinesterase test system is a device intended to measure cholinesterase (an enzyme that catalyzes the hydrolysis of acetylcholine to choline) in human specimens. There are two principal types of cholinesterase in human tissues. True cholinesterase is present at nerve endings and in erythrocytes (red blood cells) but is not present in plasma. Pseudo cholinesterase is present in plasma and liver but is not present in erythrocytes. Measurements obtained by this device are used in the diagnosis and treatment of cholinesterase inhibition disorders (e.g., insecticide poisoning and succinylcholine poisoning).

The method is based on the recommendations of the German Society for Clinical Chemistry (Deutsche Gesellschaft für Klinische Chemie, DGKCh).

Cholinesterase catalyses the hydrolysis of butyrylthiocholine to butyrate and thiocholine. Thiocholine reduces yellow hexacyanoferrate (III) to colorless hexacyanoferrate (II). The decrease in absorbance at 410 nm is directly proportional to the cholinesterase activity in the sample.

6.0 Intended Use:

System reagent for the quantitative determination of Cholinesterase activity (E.C. 3.1.1.8) in human serum and plasma on Beckman Coulter Synchron CX® Pro System(s), Synchron LX® Pro System(s) and UniCel® Dx C 600/800 System(s).

Measurements obtained by this device are used in the diagnosis and treatment of cholinesterase inhibition disorders (e.g., insecticide poisoning and succinylcholine poisoning).

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 Cholinesterase (CHE) Assay	Current device: SYNCHRON® Systems Cholinesterase (CHEX) Reagent
Intended Use	same
Methodology	same
Reagent Constituents	same
Fundamental Technology: chromogenic colored change measured by spectrophotometer	same
Analytic Interval	same
Expected Values	same
Sensitivity	same
Within run precision	same
Total precision	same
LIQUID stable reagents (ready to use)	same
On board, open reagent stability	same

List of design inputs that are different between the two devices

	Predicate Device: Olympus Cholinesterase (CHE) Assay	Current device: SYNCHRON® Systems Cholinesterase (CHEX) Reagent
System use	AU400/400e/480, AU600/640/640e and AU2700/5400	CX5 PRO, CX9 PRO, LX20 PRO, DxC600, DxC 800
Sample type	Serum, Plasma (Li Heparin, Na Heparin, EDTA)	Serum, Plasma (Li Heparin, Na Heparin)
Interfering substances	Hemoglobin: 500 mg/dL Bilirubin: 40 mg/dL Lipemia: ≤ 1000 mg/dL (Intralipid) Ascorbic Acid: 20 mg/dL	Hemoglobin: 1000 mg/dL Bilirubin: 60 mg/dL Lipemia: 2000 mg/dL (triglyceride) Ascorbic Acid: 30 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.



Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993

FEB 07 2011

Beckman Coulter, Inc.
C/O Ms. Yvette Lloyd
250 S. Kraemer Blvd.
Brea, CA 92821

Re: k103373

Trade/Device Name: SYNCHRON Systems Cholinesterase (CHEX) assay
Regulation Number: 21 CFR 862.3240
Regulation Name: Cholinesterase test system
Regulatory Class: Class I Reserved
Product Code: DIH
Dated: November 16, 2010
Received: November 17, 2010

Dear Ms. 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.

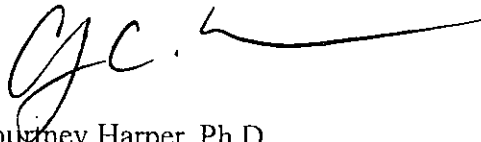
If your device is classified (see above) into class II (Special Controls), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements 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). 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 advice for your device on our labeling regulation (21 CFR Parts 801 and 809), 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 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) 796-7100 or at its Internet address <http://www.fda.gov/cdrh/industry/support/index.html>.

Sincerely yours,

A handwritten signature in black ink, appearing to read 'CHC', with a long horizontal line extending to the right.

Courtney 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 Form

510(k) Number (if known): K103373

Device Name: CHEX (Cholinesterase)

Indications for Use:

System reagent for the quantitative determination of Cholinesterase activity (E.C. 3.1.1.8) in human serum and plasma on Beckman Coulter Synchron CX[®] Pro System(s), Synchron LX[®] Pro System(s) and UniCel[®] Dx_C 600/800 System(s).

Measurements obtained by this device are used in the diagnosis and treatment of cholinesterase inhibition disorders (e.g., insecticide poisoning and succinylcholine poisoning).

Prescription Use X AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (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 Devices (OIVD)



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

510(k) K103373

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