K091846

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Summary of Safety & Effectiveness
SYNCHRON® Systems
G7 Amylase (AMY7) Reagent

1.0 **Submitted By:**

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OCT 16 2009

2.0 **Date Submitted:**

June 19, 2009

3.0 **Device Name(s):**

3.1 **Proprietary Names**
SYNCHRON® Systems G7 Amylase (AMY7) Reagent

3.2 **Classification Name**
Amylase test system (21 CFR § 862.1070)

4.0 **Predicate Device:**

Candidate(s)	Predicate	Manufacturer	Docket Number
SYNCHRON Systems G7 Amylase (AMY7) Reagent	Amylase EPS Reagent	Thermo Fisher Scientific, Inc.	K070064

5.0 **Description:**

AMY7 reagent is used to measure the amylase activity by an enzymatic rate method. The system monitors the change in absorbance at 410 nanometers. This change in absorbance is directly proportional to the activity of AMY7 in the sample and is used by the System to calculate and express the total AMY7 activity.

The SYNCHRON G7 Amylase (AMY7) Reagent is designed for optimal performance on the SYNCHRON LX®, UniCel® DxC 600/800, and SYNCHRON CX® PRO Clinical Systems. The reagent kit contains two 200-test cartridges.

6.0 **Intended Use:**

AMY7 reagent, in conjunction with SYNCHRON® System(s) and UniCel® DxC System(s), is intended for the quantitative determination of total Amylase activity in human serum, plasma or urine.

Amylase measurements are used primarily in the diagnosis and treatment of pancreatitis.

7.0 **Comparison to Predicate(s):**

The following table shows similarities and differences between the predicate identified in Section 4.0 of this summary and the G7 Amylase (AMY7) Reagent.

	Similarities	
SYNCHRON Systems G7 Amylase (AMY7) Reagent	Intended Use	Same
	Sample Types	Same
	Instrument Platforms	Same
	Primary Detection Wavelength	Same
	Reaction Type (Methodology)	Same
	Reagent Volume	AMY7 Reagent: Compartment A: 175 µl Compartment B: 35 µl EPS-G7 Reagent: Compartment A: 175 µl Compartment B: 35 µl
	Differences	
SYNCHRON Systems G7 Amylase (AMY7) Reagent	Analytical range (Serum/Plasma/ Urine)	AMY7 Reagent: 8 – 1200 U/L on CX PRO 5 – 1200 U/L on LX/DxC 1000 – 2000 U/L ORDAC EPS-G7 Reagent: 4 – 1800 U/L on CX 4 – 2000 U/L on LX/DxC
	Open reagent stability	AMY7 Reagent: 21 days EPS-G7 Reagent: 35 days
	Sample volume	AMY7 Reagent: 7 µl 3 µl ORDAC EPS-G7 Reagent: 7 µl

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.

Serum Method Comparison Summary

Candidate	Platform	Slope	Intercept	R	N	Predicate Method
G7 Amylase (AMY7) Reagent	CX7 PRO	1.150	-4.089	0.9999	87	Thermo Fisher Amylase EPS - G7 Reagent
	DxC 600	1.081	-3.364	1.0000	83	

Urine Method Comparison Summary

Candidate	Platform	Slope	Intercept	R	N	Predicate Method
G7 Amylase (AMY7) Reagent	CX7 PRO	1.109	-2.086	0.9997	78	Thermo Fisher Amylase EPS – G7 Reagent
	DxC 600	1.039	-0.703	0.9997	78	

SYNCHRON Systems G7 Amylase (AMY7) Reagent Precision Study Results

Precision Study Results on SYNCHRON CX7 PRO Clinical System

Sample		Mean (U/L)	S.D. (U/L)	%C.V.	N
Within-Run Imprecision					
Serum/Plasma	Level 1	75.8	1.3	1.7	80
Serum/Plasma	Level 2	899.5	4.7	0.5	80
Serum/Plasma	(ORDAC)	1762.0	12.9	0.7	80
Urine	Level 1	54.9	1.3	2.4	80
Urine	Level 2	164.6	1.7	1.1	80
Urine	(ORDAC)	1182.9	11.8	1.0	80
Total Imprecision					
Serum/Plasma	Level 1	75.8	1.4	1.8	80
Serum/Plasma	Level 2	899.5	8.2	0.9	80
Serum/Plasma	(ORDAC)	1762.0	34.9	2.0	80
Urine	Level 1	54.9	1.4	2.5	80
Urine	Level 2	164.6	1.9	1.2	80
Urine	(ORDAC)	1182.9	60.4	5.1	80

Precision Study Results on UniCel DxC 600 SYNCHRON Clinical System

Sample		Mean (U/L)	S.D. (U/L)	%C.V.	N
Within-Run Imprecision					
Serum/Plasma	Level 1	78.7	1.0	1.3	80
Serum/Plasma	Level 2	913.6	4.5	0.5	80
Serum/Plasma	(ORDAC)	1775.4	8.7	0.5	80
Urine	Level 1	56.5	0.7	1.2	80
Urine	Level 2	168.4	0.9	0.5	80
Urine	(ORDAC)	1181.0	6.0	0.5	80
Total Imprecision					
Serum/Plasma	Level 1	78.7	0.8	1.1	80
Serum/Plasma	Level 2	913.6	5.5	0.6	80
Serum/Plasma	(ORDAC)	1775.4	11.0	0.6	80
Urine	Level 1	56.5	0.7	1.2	80
Urine	Level 2	168.4	1.1	0.7	80
Urine	(ORDAC)	1181.0	55.5	4.7	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

Food and Drug Administration
10903 New Hampshire Avenue
Document Mail Center – WO66-0609
Silver Spring, MD 20993-0002

Beckman Coulter, Inc.
ATTN: Ms. Marine Boyajian
Senior Regulatory Affairs Specialist
200 South Kraemer Blvd. W-110
Brea, CA 92822

OCT 16 2009

Re: k091846
Trade/Device Name: Synchron® Systems G7 Amylase (AMY7) Reagent
Regulation Number: 21 CFR §862.1070
Regulation Name: Amylase test system.
Regulatory Class: Class II
Product Code: JFJ
Dated: September 11, 2009
Received: September 14, 2009

Dear Ms. Boyajian:

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

Indication for Use

510(k) Number: k091846

Device Name: SYNCHRON® Systems G7 Amylase (AMY7) Reagent

Indication For Use:

AMY7 reagent, in conjunction with SYNCHRON® System(s) and UniCel® DxC System(s), is intended for the quantitative determination of total Amylase activity in human serum, plasma or urine.

Amylase measurements are used primarily in the diagnosis and treatment of pancreatitis.

Prescription Use __X__ (21 CFR Part 801 Subpart D) And/Or Over the Counter Use ____. (21 CFR Part 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE; CONTINUE ON ANOTHER PAGE IF 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) K091846