TECO DIAGNOSTICS

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Updated 510K summary
Teco CX3 Reagent Set for SYNCHRON CX
Contact Name: Jian Vaeches
Phone Number: 714-693-7788 ext.131
Prepared Date: 03/20/2006

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Device Name

The device trade names and common/classifications name are:

Device Trade Name	Common/Classification Name
Teco CX3 Reagent Set for SYNCHRON CX System	BUN, CALCIUM, CREATININE ,GLUCOSE REGENTS

Address and Registration

The address and registration number of the manufacturer site for Teco CX3 Reagent Set for SYNCHRON CX System:

TECO Diagnostics
1268 N. Lakeview Ave.
Anaheim, CA 92807, U.S.A.
FDA Registration # 1832216

Device Classs

Teco CX3 Reagent Set has been classified as Class II with Product Code ~~LPP~~ CDQ, ~~JPP~~ CIC, CGX, CGA "in vitro" diagnostics reagent set having the classification number: 21 CFR. 862.1770, 21 CFR 862.1145, 21 CFR 862.1225, 21 CFR 862.1345. This is the description available from the classification names listed in the " CDRH Home Page- Listing Database."

Predicate Device Information

The predicate device is Teco BUN Liquid, Teco Calcium Color, Teco Creatinine and Teco Glucose Liquid Reagent.
The 510 (K) approval letter is provided in Appendix I.
510(K) #: K981106, K864741, K880629, K863926.
Approval Date: 04-16-1998, 01-09-1987, 03-23-1988, 11-13-1986

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Labeling and Intended Use

Draft labels and Instructions for use can be found in appendix A.

Intended Use
Teco CX3 Reagent Set for SYNCHRON CX is intended for the quantitative determination of BUN, Calcium, Creatinine and Glucose in serum on Beckman CX3 System.

Device Description and Comparison

The Teco CX3 Reagent Set for SYSNCHRON CX designed for use on the Beckman CX System. The Reagent Set includes BUN, Calcium, Creatinine and Glucose.
Method Comparison of Teco CX3 Reagent Set for SYNCHRON CX to Teco BUN Liquid, Teco Calcium Color, Teco Creatinine and Teco Glucose Liquid following the guidelines of NCCLS Guideline EP9-A2 was conducted.
Comparison with predicate:
Similarities
Intended use.
Sample Handling Subsystem.
Operational Environment
Performance.

Differences

	Predicate Device	**Candidate Device**
Packaging Size		
BUN	5 x 25 ml & 5 x 5 ml	500 ml
Calicium	4 x 120 ml	500 ml
Creatinine	4 x 120 ml	2000 ml
Glucose	4 x 120 ml	500 ml
Analyzer	General Chemistry Analyzers	SYSCHRON CX3
Components		
BUN	Tris Buffer 100 mmol	Urease >592 U/ml
	2-Oxoglutarate 5 mmol	
	Urease >20,000 U/L	
	GLDH > 1500 U/L	
	NADH 0.25 mmol/L	
	Predicate Device	**Candidate Device**

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Calcium	O-Cresolphthalein Complexone 0.14 mM	Arsenazo III 0.15 mml/L
	8-Hydroxyquinoline 13 mM	
	Diethylamide 363 mM	
Creatinine	Picric Acid 10mM	Picric Acid 50mM
	Sodium Hydroxide 240mM	Sodium Hydroxide 0.188 mM
Glucose	Glucose Oxidase 15 u/ml	Glucose Oxidase 590 u/ml
	Peroxidase 1.2 u/ml	Ethanol 10%
	4-Aminoantipyrine 0.38 mM	Potassium Iodide 0.04 mM
	p-Hydroxybenzene Sulfonate 10 mM	

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Standard/ Guidance Document Referenced (if applicable)

NCCLS EP5-A—Evaluation of Precision Performance of Clinical Chemistry Devices
NCCLS EP6-A--- Evaluation of Linearity of Quantitative Analytical Methods
NCCLS EP9-A---Method Comparison and Bias Estimation Using Patient Samples

Test Principle

BUN (Urea Nitrogen) is hydrolyzed by urease to produce ammonium and bicarbonate which resulted in the increase of solution conductivity which is directly proportional to the concentration of BUN present in the test.

Calcium reacts with Arsenazo to form an bluish-purple colored chromophore which is measured spectrophotometrically at 650 nm. A reagent blank reading is taken just prior to sample injection, and a final absorbance reading is taken 21 seconds later. The differential absorbance, corrected for the reagent blank, is directly proportional to the calcium concentration.

Creatinine from the sample combines with the reagent to produce a red color complex. Absorbance reading is taken at both 520nm and 560nm at 25.6 seconds after picking up sample. The differential absorbance has been shown to be a direct measure of the concentration of creatinine in the sample.

SYSNCHRON CX3 determines glucose concentration by an oxygen rate method using a glucose Oxygen electrode. The rate of oxygen depletion is proportional to the glucose concentration in the samples.

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Substantial Equivalence

The Teco CX3 Reagent Set for SYNCHRON CX System is substantially equivalent to other devices legally marketed in the United States. We have compared TECO Diagnostics Teco CX3 Reagent Set for SYNCHRON CX System to TECO Diagnostics Teco BUN Liquid, Teco Calcium Color, Teco Creatinine and Teco Glucose Liquid Reagent for Hitachi.The 510 (K) numbers are K981106, K864741, K880629, and K863926. Both devices are for the quantitative determination of the same analyst in serum.

Summary of Design Control Activities

The risk analysis method used to assess the impact of modifications was a Failure Modes and Effects Analysis (FMEA). The design verification tests that were performed as a result of this risk analysis assessment are listed in table 1&2 below. The tests data can also be found in appendix C through F.

1. Table 1 – **Performance Characteristics (Human Serum)**

BUN:

Feature	Predicate Device		Candidate Device		
Precision Within-Day	Sample 1 N=20 Mean=12.9 SD=0.33 CV%=2.62	Sample 2 N=20 Mean=51.8 SD=0.74 CV%=1.43	Sample 1 N=25 Mean=18 SD=0.46 CV%=2.5	Sample 2 N=25 Mean=49 SD=0.91 CV%=1.9	Sample 3 N=25 Mean=97.5 SD=1.3 CV%=1.3
Day to Day	Sample 1 N=20 Mean=12.4 SD=0.15 CV%=1.2	Sample 2 N=20 Mean=44.6 SD=0.75 CV%=1.67	Sample 1 N=25 Mean=18 SD=0.37 CV%=2.0	Sample 2 N=25 Mean=49 SD=1.04 CV%=2.0	Sample 3 N=25 Mean=98 SD=1.14 CV%=1.1

Teco CX3 Reagent Set, the acceptability of CV% in BUN test is within 8%

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Calcium:

Feature	Predicate Device		Candidate Device		
Precision Within-Day	Sample 1 N=20 Mean=9.1 SD=0.39 CV%=4.3	Sample 2 N=20 Mean=13.7 SD=0.02 CV%=0.2	Sample 1 N=25 Mean=9.1 SD=0.08 CV%=0.9	Sample 2 N=25 Mean=12.3 SD=0.11 CV%=0.9	Sample 3 N=25 Mean=14 SD=0.16 CV%=0.8
Day to Day	Sample 1 N=20 Mean=9.2 SD=0.21 CV%=2.2	Sample 2 N=20 Mean=13.3 SD=0.32 CV%=2.4	Sample 1 N=25 Mean=9.1 SD=0.09 CV%=1.0	Sample 2 N=25 Mean=12.4 SD=0.14 CV%=1.1	Sample 3 N=25 Mean=14 SD=0.14 CV%=1.0

Teco CX3 Reagent Set, the acceptability of CV% in Calcium test is within 5%

Creatinine:

Feature	Predicate Device		Candidate Device		
Precision Within-Day	Sample 1 N=20 Mean=1.9 SD=0.05 CV%=2.6	Sample 2 N=20 Mean=8.2 SD=0.6 CV%=7.3	Sample 1 N=25 Mean=1.3 SD=0.04 CV%=2.7	Sample 2 N=25 Mean=6.4 SD=0.11 CV%=1.6	Sample 3 N=25 Mean=20 SD=0.35 CV%=1.7
Day to Day	Sample 1 N=20 Mean=2.0 SD=0.2 CV%=10	Sample 2 N=20 Mean=8.2 SD=0.4 CV%=4.6	Sample 1 N=25 Mean=1.3 SD=0.03 CV%=2.2	Sample 2 N=25 Mean=6.6 SD=0.24 CV%=3.7	Sample 3 N=25 Mean=19.9 SD=0.33 CV%=1.6

Teco CX3 Reagent Set, the acceptability of CV% in Creatinine test is within 10%

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Glucose:

Feature	Predicate Device		Candidate Device		
Precision Within-Day	Sample 1 N=20 Mean=87 SD=4.2 CV%=4.8	Sample 2 N=20 Mean=282 SD=5.4 CV%=1.9	Sample 1 N=25 Mean=78 SD=2.0 CV%=2.5	Sample 2 N=25 Mean=255 SD=3.4 CV%=1.3	Sample 3 N=25 Mean=735 SD=9.8 CV%=1.5
Day to Day	Sample 1 N=20 Mean=85 SD=3.7 CV%=4.3	Sample 2 N=20 Mean=287 SD=9.6 CV%=3.3	Sample 1 N=25 Mean=79 SD=2.6 CV%=3.3	Sample 2 N=25 Mean=262 SD=5.9 CV%=2.2	Sample 3 N=25 Mean=734 SD=8.7 CV%=1.2

Teco CX3 Reagent Set, the acceptability of CV% in Glucose test is within 10%

Table 2-**Performance Characteristics (Human Serum)**

BUN:

Feature	Candidate Device	Predicate Device
Linearity	3 to 102 mg/dL	up to 80 mg/dL
Accuracy	R=0.99 Y=1.00 -0.911	R=0.99 Y=0.962 X – 0.721
Expect values/ Reference range	15-39 mg/dL	8-23 mg/L

Teco CX3 Reagent Set BUN test, Acceptance Criteria of Accuracy: r > 0.95; Slope: 0.97-1.1

Calcium:

Feature	Candidate Device	Predicate Device
Linearity	1.0 to 15 mg/dL	up to 20 mg/dL
Accuracy	R=0.96 Y=1.07X +0.60	R=0.97 Y=0.94 X+ 0.53
Expect values/ Reference range	8.4-10.2 mg/dL	8.5-10.5 mg/dL

Teco CX3 Reagent Set Calcium test, Acceptance Criteria of Accuracy: r > 0.90; Slope: 0.90-1.1

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Creatinine:

Feature	Candidate Device	Predicate Device
Linearity	0.2 to24g/dL	Up to 25 mg/dL
Accuracy	R=0.99 Y=0.97 -0.11	R=0.99 Y=0.96 X+ 0.06
Expect values/ Reference range	0.6-1.3 mg/dL	Male: 0.9-1.5 mg/dL Female: 0.7-1.37 mg/dL

Teco CX3 Reagent Set Creatinine test, Acceptance Criteria of Accuracy: r > 0.96; Slope: 0.90-1.1

Glucose:

Feature	Candidate Device	Predicate Device
Linearity	30 to 750 mg/dL	up to 500 mg/dL
Accuracy	R=0.99 Y=0.96X+0.36	R=0.99 Y=1.02 X+3.1
Expect values/ Reference range	70-105 mg/dL	70-106 mg/dL

Teco CX3 Reagent Set Glucose test, Acceptance Criteria of Accuracy: r > 0.90; Slope: 0.85-1.1

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

MAR 2 7 2006

Ms. Jian Vaeches
Teco Diagnostics
1268 N. Lakeview Ave
Anaheim, CA 92807

Re: k060120
Trade/Device Name: Teco CX3 Reagent Set for SYNCHRON CX System
Regulation Number: 21 CFR§ 862.1770
Regulation Name: Urea nitrogen test system
Regulatory Class: Class II
Product Code: CDQ, CIC, CGX, CGA
Dated: March 16, 2006
Received: March 16, 2006

Dear Ms. Vaeches:

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 (240) 276-0484. 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/industry/support/index.html.

Sincerely yours,

Alberto Gutierrez, 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): k060120

Device Name: Teco CX3 Reagent Set for SYNCHRON CX System

Indications For Use: Teco CX3 Reagent Set for SYNCHRON CX System is intended for the quantitative determination of BUN, Calcium, Creatinine and Glucose in serum on Beckman CX3 System.

BUN measurements are used in the diagnosis and treatment of certain renal and metabolic diseases.

Calcium measurements are used in the diagnosis and treatment of parathyroid diseases, a variety of bone diseases, chronic renal and tetany.

Creatinine measurements are used in the diagnosis and treatment of renal diseases, in monitoring renal dialysis, and a calculation basis for measuring other urine analytes.

Glucose measurements are used in the diagnosis and treatment of carbohydrate metabolism disorders, including diabetes mellitus, neonatal hypoglycemia and idiopathic hypoglycemia, and pancreatic islet carcinoma.

This reagent set is intended for *in vitro* diagnostic use only.

Prescription Use √ AND/OR Over-The-Counter Use

(Part 21 CFR 801.109)

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

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

...sion Sign-Off

Office of In Vitro Diagnostic Device Evaluation and Safety

...) K060120