K042291

NOV 12 2004

510(k) Summary
UniCel® DxC SYNCHRON® Clinical Systems

1.0 **Submitted By:**

Mary Beth Tang
Staff Regulatory Affairs Specialist
Beckman Coulter, Inc.
200 S. Kraemer Blvd., W-104
Brea, California 92822-8000
Telephone: (714) 961-3777
FAX: (714) 961-4123

2.0 **Date Submitted:**

August 23, 2004

3.0 **Device Name(s):**

3.1 **Proprietary Names**
UniCel® DxC 600 SYNCHRON® System
UniCel® DxC 800 SYNCHRON® System

3.2 **Classification Name**
Discrete photometric chemistry analyzer for clinical use [862.2160]

4.0 **Predicate Device:**

Candidate(s)	Predicate	Manufacturer	Docket #
UniCel® DxC 600 SYNCHRON® System	SYNCHRON LX®20 PRO Systems	Beckman Coulter, Inc.*	K965240, K011213
UniCel® DxC 800 SYNCHRON® System			

*Beckman Coulter, Inc., Brea, CA

5.0 **Description:**

The UniCel DxC 600 and 800 Systems are the next generation of clinical chemistry analyzers in Beckman Coulter's SYNCHRON instrument family. The analyzers operate in conjunction with reagents, calibrators, and controls designed for use with SYNCHRON Systems. The DxC instruments feature bar code identification of samples and reagents, Closed Tube Sampling, Obstruction Detection and Correction, and a dual carousel reagent storage compartment with an onboard capacity of 59 cartridges. Major system components include sample and reagent handling systems, bar code readers, modular chemistry sections, cartridge chemistry systems, and reagent storage compartment, supported by power and hydropneumatic utilities.

6.0 **Intended Use:**

The UniCel DxC SYNCHRON Systems are fully automated, computer-controlled clinical chemistry analyzers intended for the in vitro determination of a variety of general chemistries, therapeutic drugs, and other chemistries of clinical interest in biological fluids such as serum, plasma, urine, or cerebrospinal fluid, (sample type is chemistry dependent).

7.0 Comparison to Predicate(s):

	Similarities	
UniCel DxC 600 and 800 Systems	Intended Use	Same as Beckman Coulter SYNCHRON LX PRO Systems
	Fundamental Technologies	
	Operational Environment	
	System Architecture	
	Optics/Reaction Subsystem	
	Sample Handling Subsystem	
	Chemistry Databases	
	Reagents and Consumables	
	Differences	
	Reagent Storage Capacity	LX: 30 cartridges DxC 600/800: 59 cartridges
	Reagent Handling Subsystem	LX: Teflon coated high nickel steel probes DxC 600/800: Extended length design
	Instrument Packaging	LX: 70 inch width DxC 600: 62 inch width DxC 600/800: New instrument skins
	Subsystem Designs	LX: Original DxC 600/800: Modified Modular Chemistry, Power, and Hydropneumatic subsystems
	Electronics	LX: Original DxC 600/800: New components to address obsolescence issues
	Operator Interface	LX: Original DxC 600/800: New key features
	Maintenance Procedures	LX: Chloride electrode resurfacing DxC 600/800: Replaceable chloride electrode tip
	Modular Chemistry Menu	LX: 11 chemistries DxC 600: 6 chemistries
	Cartridge Chemistry Menu	LX: 83 chemistries DxC 600/800: 86 chemistries

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 and imprecision studies.

UniCel DxC 800 System vs. SYNCHRON LX20 PRO Serum Correlation Study

Modular Assays	N	Slope	Intercept	R	Cartridge Assays	N	Slope	Intercept	R
NA	164	0.987	1.99	0.996	CRPH	94	1.024	-0.03	0.999
K	161	0.993	0.07	0.998	FE	141	1.002	-0.16	1.000
CL	194	1.005	-0.86	0.997	LD	181	1.005	5.54	0.999
CO2	219	1.043	-1.05	0.994	MG	175	0.969	0.04	0.999
CAL	184	1.007	-0.03	0.999	PHE	91	0.981	0.02	0.998
ALBm	158	0.990	0.05	1.000	URIC	112	1.017	-0.08	1.000
BUNm	111	0.985	0.31	1.000					
CREm	137	1.037	-0.01	1.000	Qualitative Drug Assay (urine)				
GLUm	199	1.006	-0.11	1.000	BENZ	+	-	Agreement	
PHOSm	198	1.004	0.02	0.999	+	43	0	100%	
TPm	191	0.992	0.08	0.996	-	0	57		

Unicel 800 System Estimated Serum Imprecision (N=80)

Chemistry	Control Level	Mean	Within-run SD	Within-run %CV	Total SD	Total %CV
NA	Low	114.8 mmmol/L	0.65	0.6	1.0	0.9
	High	155.6 mmol/L	0.96	0.6	1.32	0.9
K	Low	2.39 mmol/L	0.025	1.0	0.030	1.2
	High	7.30 mmol/L	0.056	0.8	0.063	0.9
CL	Low	81.8 mmol/L	0.77	0.9	1.00	1.2
	High	122.2 mmol/L	0.92	0.8	1.20	1.0
CO2	Low	12.2 mmol/L	0.39	3.2	0.49	4.0
	High	31.5 mmol/L	0.55	1.7	0.64	2.0
CALC	Low	7.5 mg/dL	0.07	0.9	0.08	1.0
	High	13.6 mg/dL	0.09	0.6	0.14	1.1
ALBm	Low	2.3 g/dL	0.04	1.9	0.06	2.4
	High	5.1 g/dL	0.05	1.0	0.06	1.1
BUNm	Low	6.8 mg/dL	0.4	6.2	0.5	6.9
	High	61.4 mg/dL	1.7	2.8	1.7	2.8
CREm	Low	0.5 mg/dL	0.04	8.7	0.04	9.0
	High	7.9 mg/dL	0.09	1.2	0.18	2.3
GLUm	Low	43.2 mg/dL	1.17	2.7	1.51	3.5
	High	379.0 mg/dL	2.11	0.6	4.88	1.3
PHOSm	Low	1.8 mg/dL	0.04	1.9	0.05	2.7
	High	6.5 mg/dL	0.06	1.0	0.11	1.7
TPm	Low	3.6 g/dL	0.08	2.4	0.09	2.5
	High	7.8 g/dL	0.08	1.0	0.10	1.2
BENZ	Low	413.1 mA/min	2.35	0.6	3.61	0.9
	High	470.0 mA/min	2.58	0.6	3.87	0.8
CRPH	Low	0.08 mg/dL	0.004	5.3	0.004	5.3
	High	7.59 mg/dL	0.135	1.8	0.153	2.0
FE	Low	65.0 µg/dL	1.82	2.8	2.14	3.3
	High	260.6 µg/dL	3.43	1.3	4.04	1.6
LD	Low	53 IU/L	2.3	4.4	2.4	4.5
	High	383 IU/L	4.1	1.1	6.5	1.7
MG	Low	1.2 mg/dL	0.01	1.2	0.02	2.1
	High	3.5 mg/dL	0.05	1.6	0.07	2.0
PHE	Low	9.3 µg/mL	0.19	2.1	0.25	2.7
	High	67.7 µg/mL	1.73	2.6	2.56	3.8
URIC	Low	2.5 mg/dL	0.05	2.0	0.05	2.1
	High	11.0 mg/dL	0.06	0.6	0.07	0.7

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.

BECKMAN COULTER

August 9, 2004

Software Development Statement of Compliance

The UniCel^{R} DxC 600/800 SYNCHRON^{R} Systems Software Version 1.0 was developed in compliance with internal procedure 12-0101 Software Development: Description of the Software Development Process 9/16/2002. Each phase of this software process model, Planning, Requirements, Design, Implementation and Validation was completed, verified and documented. Documentation is stored in the Software Central Project File Section 4.

The specific application of Procedure 12-0101 to UniCel^{R} DxC 600/800 SYNCHRON^{R} Systems Software Version 1.0 is detailed in the Software Development Plan. The software was validated according to the Software Validation Plan. Discrepancies between expected performance and final outcomes were managed through the software change control process in compliance with section 4 of Procedure 12-0101. The software validation report is included as an addendum to the Software Validation Plan.

An independent review of the software development documentation and validation reports ensured that each phase was completed as planned and the resulting product meets the acceptance criteria.

Gayle A. Nobbs
Center Manager - Software Development
Laboratory Systems and Routine Testing Platform Development

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

NOV 12 2004

Ms. Mary Beth Tang
Staff Regulatory Affairs Specialist
Beckman Coulter, Inc.
200 S. Kraemer Blvd., W-104
P.O. Box 8000
Brea, CA 92822-8000

Re: k042291
Trade/Device Name: UniCel® DxC 600 SYNCHRON® Clinical System
UniCel® DxC 800 SYNCHRON® Clinical System
Regulation Number: 21 CFR 862.1660
Regulation Name: Potassium test system
Regulatory Class: Class II
Product Code: CEM, CEK CEO, CFJ, CGA, CGX, CGZ, CJW, DCK, DLZ, JFL, JFP, JGJ, JGS, JHB, JIY, JJE, JXM, LFP
Dated: October 13, 2004
Received: October 15, 2004

Dear Ms. Tang:

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,

Cornelia B. Rooks

Cornelia B. Rooks, MA
Acting 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): K042291

Device Name: **UniCel® DxC 600 SYNCHRON® Clinical System**
UniCel® DxC 800 SYNCHRON® Clinical System

Indications for Use:

The UniCel DxC SYNCHRON Systems are fully automated, computer-controlled clinical chemistry analyzers intended for the in vitro determination of a variety of general chemistries, therapeutic drugs, and other chemistries of clinical interest in biological fluids such as serum, plasma, urine, or cerebrospinal fluid, (sample type is chemistry dependent).

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)

Albert C
Division Sign-Off

Office of In Vitro Diagnostic
Device Evaluation and Safety

510(k) K042291

Indications for Use

510(k) Number (if known):

[redacted]

Device Name:

SYNCHRON® Systems Total Protein (TP) Reagent

Indications for Use:

TP reagent, when used in conjunction with UniCel® DxC 600/800 Systems and SYNCHRON® Systems Multi Calibrator, is intended for the quantitative determination of Total Protein concentration in human serum or plasma.

Total protein measurements are used in the diagnosis and treatment of diseases involving the liver, kidney or bone marrow, as well as other metabolic or nutritional disorders.

Prescription Use ____X_____ 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

510(k) K042291

Indications for Use

510(k) Number (if known):

[redacted]

Device Name:

SYNCHRON® Systems Total Protein (TPm) Reagent

Indications for Use:

TPm reagent, when used in conjunction with SYNCHRON LX® Systems, UniCel® DxC 800 Systems and SYNCHRON® Systems Protein Calibrator, is intended for the quantitative determination of Total Protein concentration in human serum, plasma or cerebrospinal fluid (CSF).

Total protein measurements are used in the diagnosis and treatment of diseases involving the liver, kidney or bone marrow, as well as other metabolic or nutritional disorders.

Prescription Use ____X_____ 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

510(k) k042991

Indications for Use

510(k) Number (if known):

[redacted]

Device Name:

SYNCHRON® Systems Potassium (K) Assay

Indications for Use:

ISE Electrolyte Buffer reagent and ISE Electrolyte Reference reagent, when used in conjunction with SYNCHRON LX® Systems, UniCel® DxC 600/800 Systems and SYNCHRON® Systems AQUA CAL 1, 2 and 3, are intended for the quantitative determination of Potassium concentration in human serum, plasma or urine.

Potassium measurements are used in the diagnosis and treament of hypokalemia, hyperkalemia, renal failure, Addison's disease or other diseases involving electrolyte imbalance.

Prescription Use ____X_____ 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

510(k) k042291

Indications for Use

510(k) Number (if known):

[redacted]

Device Name:

SYNCHRON® Systems Phosphorus (PHOSm) Reagent

Indications for Use:

PHOSm reagent, when used in conjunction with SYNCHRON LX® Systems, UniCel® DxC 800 Systems and the SYNCHRON® Systems AQUA CAL 1 and 2, is intended for the quantitative determination of inorganic Phosphorus concentration in human serum, plasma or urine.

Measurements of phosphorus (inorganic) are used in the diagnosis and treatment of various disorders, including parathyroid gland and kidney diseases, and vitamin D imbalance.

Prescription Use ____X_____ 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

510(k) K042291

Indications for Use

510(k) Number (if known):

[redacted]

Device Name:

SYNCHRON® Systems Lactate Dehydrogenase (LD) Reagent

Indications for Use:

LD reagent, when used in conjunction with SYNCHRON LX® Systems or UniCel® DxC 600/800 Systems, is intended for the quantitative determination of Lactate Dehydrogenase activity in human serum or plasma.

Lactate dehydrogenase measurements are used in the diagnosis and treatment of liver diseases such as acute viral hepatitis, cirrhosis, and acute metastatic carcinoma of the liver, cardiac diseases such as myocardial infarction, and tumors of the lung or kidneys.

Prescription Use ____X_____ 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

510(k) K042291

Indications for Use

510(k) Number (if known):

[redacted]

Device Name:

SYNCHRON® Systems Glucose (GLUCm) Reagent

Indications for Use:

GLUCm reagent, when used in conjunction with SYNCHRON LX® Systems, UniCel® DxC 600/800 Systems and SYNCHRON® Systems AQUA CAL 1 and 2, is intended for the quantitative determination of Glucose concentration in human serum, plasma, urine or cerebrospinal fluid (CSF).

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

Prescription Use ____X_____ 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

510(k) K042291

Indications for Use

510(k) Number (if known):

[redacted]

Device Name:

SYNCHRON® Systems Creatinine (CREm) Reagent

Indications for Use:

CREm reagent, when used in conjunction with SYNCHRON LX® Systems, UniCel® DxC 800 Systems and SYNCHRON® Systems AQUA CAL 1 and 2, is intended for the quantitative determination of Creatinine concentration in human serum, plasma or urine.

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

Prescription Use ____X_____ 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

510(k) K042291

Indications for Use

510(k) Number (if known):

[redacted]

Device Name:

SYNCHRON® Systems Creatinine (CREA) Reagent

Indications for Use:

CREA reagent, when used in conjunction with UniCel® DxC 600/800 Systems and SYNCHRON® Systems Multi Calibrator, is intended for the quantitative determination of Creatinine concentration in human serum, plasma or urine.

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

Prescription Use ____X_____ 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

510(k) K042291

Indications for Use

510(k) Number (if known):

[redacted]

Device Name:

SYNCHRON® Systems Chloride (CL) Assay

Indications for Use:

ISE Electrolyte Buffer reagent and ISE Electrolyte Reference reagent, when used in conjunction with SYNCHRON LX® Systems, UniCel® DxC 600/800 Systems and SYNCHRON® Systems AQUA CAL 1 and 2, are intended for quantitative determination of Chloride concentration in human serum, plasma, urine or cerebrospinal fluid (CSF).

Chloride measurments are used in the diagnosis and treatment of electrolyte and metabolic disorders such as cystic fibrosis and diabetic acidosis.

Prescription Use ____X_____ 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

510(k) K042291

Indications for Use

510(k) Number (if known)

[redacted]

Device Name:

SYNCHRON® Systems Albumin (ALB) Reagent

Indications for Use:

ALB reagent, when used in conjunction with UniCel® DxC 600/800 Systems and SYNCHRON® Systems Multi Calibrator, is intended for the quantitative determination of Albumin concentration in human serum or plasma.

Albumin measurements are used in the diagnosis and treatment of numerous diseases primarily involving the liver and/or kidneys.

Prescription Use ____X_____ 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

510(k) K042291

Indications for Use

510(k) Number (if known):

[redacted]

Device Name:

SYNCHRON® Systems Albumin (ALBm) Reagent

Indications for Use:

ALBm reagent, when used in conjunction with SYNCHRON LX® Systems, UniCel® DxC 800 Systems and SYNCHRON® Systems Protein Calibrator, is intended for the quantitative determination of Albumin concentration in human serum or plasma.

Albumin measurements are used in the diagnosis and treatment of numerous diseases primarily involving the liver and/or kidneys.

Prescription Use ____X_____ 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

510(k) K042291

Indications for Use

510(k) Number (if known):

[redacted]

Device Name:

SYNCHRON® Systems High Sensitivity C-Reactive Protein (CRPH) Reagent

Indications for Use:

High Sensitivity CRPH reagent, when used in conjunction with SYNCHRON LX® PRO Systems, UniCel® DxC 600/800 Systems, and SYNCHRON® Systems CAL 5 Plus, is intended for the quantitative determination of C-Reactive Protein in human serum or plasma by rate turbidimetry.

Measurement of C-Reactive protein aids in the evaluation of stress, trauma, infection, inflammation, surgery, and associated diseases.

Prescription Use ____X_____ 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

510(k) K042291

Indications for Use

510(k) Number (if known):

[redacted]

Device Name:

SYNCHRON® Systems Phenobarbital (PHE) Reagent

Indications for Use:

PHE reagent, when used in conjunction with SYNCHRON LX® Systems, UniCel® DxC 600/800 Systems and SYNCHRON® Systems Drug Calibrator 1, is intended for the quantitative determination of Phenobarbital concentration in human serum or plasma.

Phenobarbital is indicated for the treatment of status epilepticus, febrile seizures and seizure disorders (grand mal and psychomotor), except absence (petit mal) seizures. Phenobarbital therapy is monitored for suspected inadequate dose or toxicity.

Prescription Use ____X_____ 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

510(k) K042291

Indications for Use

510(k) Number (if known):

[redacted]

Device Name:

SYNCHRON® Systems Carbon Dioxide (CO2) Assay

Indications for Use:

ISE Electrolyte Buffer reagent, ISE Electrolyte Reference reagent, CO_2 Alkaline Buffer and CO2 Acid reagent, when used in conjunction with SYNCHRON LX® Systems, UniCel® DxC 600/800 Systems and SYNCHRON® Systems AQUA CAL 1 and 3, are intended for quantitative determination of Carbon Dioxide concentration in human serum or plasma.

Carbon dioxide measurements are used in the diagnosis and treatment of numerous potentially serious disorders associated with changes in body acid-base balance.

Prescription Use ____X_____ 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

510(k) K042291

Indications for Use

510(k) Number (if known)

[redacted]

Device Name:

SYNCHRON® Systems Calcium (CALC) Assay

Indications for Use:

ISE Electrolyte Buffer reagent and ISE Electrolyte Reference reagent, when used in conjunction with SYNCHRON LX® Systems, UniCel® DxC 600/800 Systems and SYNCHRON® Systems AQUA CAL 1 and 2, are intended for quantitative determination of Calcium concentration in human serum, plasma or urine.

Calcium measurements are used in the diagnosis and treatment of parathyroid disease, a variety of bone diseases, chronic renal disease and tetany (intermittent muscular contractions or spasms).

Prescription Use ____X_____ 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

510(k) K042291

Indications for Use

510(k) Number (if known):

[redacted]

Device Name:

SYNCHRON® Systems Magnesium (MG) Reagent

Indications for Use:

MG reagent, when used in conjunction with SYNCHRON LX® Systems, UniCel® DxC 600/800 Systems and SYNCHRON® Systems Multi Calibrator, is intended for the quantitative determination of Magnesium concentration in human serum, plasma or urine.

Determination of magnesium is useful in assessing several diseases and conditions. High magnesium is associated with uremia, dehydration, diabetic acidosis, Addison's disease, and increased medicinal intake of magnesium, such as in the treatment of preeclampsia (hypertension induced by pregnancy). Low magnesium is associated with malabsorption syndrome, acute pancreatitis, hypoparathyroidism, chronic alcoholism and delirium tremens, chronic glomerulonephritis, aldosteronism, digitalis intoxication, and protracted I.V. feeding.

Prescription Use ____X_____ 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

510(k) K042291

Indications for Use

510(k) Number (if known):

[redacted]

Device Name:

SYNCHRON® Systems Sodium (NA) Assay

Indications for Use:

ISE Electrolyte Buffer reagent and ISE Electrolyte Reference reagent, when used in conjunction with SYNCHRON LX® Systems, UniCel® DxC 600/800 Systems and SYNCHRON® Systems AQUA CAL 1, 2 and 3, are intended for the quantitative determination of Sodium concentration in human serum, plasma or urine.

Sodium measurements are used in the diagnosis and treatment of aldosteronism, diabetes insipidus, adrenal hypertension, Addison's disease, dehydration, inappropriate antidiuretic hormone secretion, or other diseases involving electrolyte imbalance.

Prescription Use ____X_____ 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

510(k) K042291

Indications for Use

510(k) Number (if known):

[redacted]

Device Name:

SYNCHRON® Systems Uric Acid (URIC) Reagent

Indications for Use:

URIC reagent, when used in conjunction with SYNCHRON LX® Systems, UniCel® DxC 600/800 Systems and SYNCHRON® Systems Multi Calibrator, is intended for quantitative determination of Uric Acid concentration in human serum, plasma, or urine.

Uric acid measurements are used in the diagnosis and treatment of numerous renal and metabolic disorders, including renal failure, gout, leukemia, psoriasis, starvation or other wasting conditions, and of patients receiving cytotoxic drugs.

Prescription Use ____X_____ 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

510(k) K042291

Indications for Use

510(k) Number (if known):

[redacted]

Device Name:

SYNCHRON® Systems Iron (FE) Reagent

Indications for Use:

FE reagent, when used in conjunction with SYNCHRON LX® Systems, UniCel® DxC 600/800 Systems and SYNCHRON® Systems FE/IBCT Calibrator Kit, is intended for the quantitative determination of Iron in human serum or heparinized plasma.

Alterations in iron and total iron binding capacity levels result from changes in iron intake, absorption, storage, and release mechanisms. Such changes are indicative of a wide range of dysfunctions including anemias, nephrosis, cirrhosis and hepatitis. Both iron and total iron binding capacity measurements are important for definitive diagnosis because they are interrelated. Tietz has presented a summary of these relationships and the patterns of iron/total iron binding capacity associated with various disease states.

Prescription Use ____X_____ 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

510(k) K042291

Indications for Use

510(k) Number (if known):

[redacted]

Device Name:

SYNCHRON® Systems Benzodiazepine (BENZ) Reagent

Indications for Use:

BENZ reagent, when used in conjunction with SYNCHRON LX® Systems, UniCel® DxC 600/800 Systems, and SYNCHRON® Systems Drugs of Abuse Testing (DAT) Urine Calibrators, is intended for the qualitative determination of Benzodiazepine in human urine at a cutoff value of 200 ng/mL (oxazepam).

The BENZ assay provides a rapid screening procedure for determining the presence of the analyte in urine. This test provides only a preliminary analytical result; a positive result by this assay should be confirmed by another generally accepted non-immunological method such as thin layer chromatography (TLC), gas chromatography (GC), or gas chromatography/mass spectrometry (GC/MS). GC/MS is the preferred confirmatory method.

Clinical consideration and professional judgement should be applied to any drug of abuse test result, particularly when preliminary positive results are used.

Benzodiazepines are a class of central nervous system depressants that are used as sedatives and hypnotics. The benzodiazepine compounds include chlordiazepoxide, diazepam, oxazepam, flurazepam, and nitrazepam. Measurements of benzodiazepines on the SYNCHRON® Systems are used in the diagnosis and treatment of benzodiazepine use and overdose, and in monitoring the presence of benzodiazepines to ensure appropriate therapy.

Prescription Use ____X_____ 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

510(k) K042291

Indications for Use

510(k) Number (if known):

[redacted]

Device Name:

SYNCHRON® Systems Urea Nitrogen (BUNm or UREAm) Reagent

Indications for Use:

BUNm or UREAm reagent, when used in conjunction with SYNCHRON LX® Systems, UniCel® DxC 800 Systems and SYNCHRON® Systems AQUA CAL 1, 2 and 3, is intended for the quantitative determination of Urea Nitrogen or Urea concentration in human serum, plasma or urine. The system can be configured to report results as either urea nitrogen in default units of mg/dL or urea in default units of mmol/L.

Urea nitrogen or urea measurements are used in the diagnosis and treatment of certain renal and metabolic diseases.

Prescription Use ____X_____ 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

510(k) K042291