200 South Kraemer Boulevard, Box 8000, Brea, CA 92822-8000 • (714) 993-5321

K965240

BECKMAN

Summary of Safety & Effectiveness
SYNCHRON LX™20 Clinical Chemistry System

1.0 Submitted By

Sheri Hall
Manager, Product Submissions
Beckman Instruments, Inc.
200 S. Kraemer Blvd. W-337
Brea, California 92822-8000
Telephone: (714) 993-8916
FAX: (714) 961-4457

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2.0 Date Submitted

25 November 1996

3.0 Device Name(s)

3.1 Proprietary Names

SYNCHRON LX™20 Clinical Chemistry System
SYNCHRON LX™ Albumin Reagent
SYNCHRON LX™ Creatinine Picric Reagent
SYNCHRON LX™ Creatinine Alkaline Reagent
SYNCHRON LX™ Glucose Reagent
SYNCHRON LX™ Phosphorus Molybdate Reagent
SYNCHRON LX™ Phosphorus Diluent Reagent
SYNCHRON LX™ Total Protein Reagent
SYNCHRON LX™ Urea Nitrogen Reagent
SYNCHRON LX™ CO2 Acid Reagent
SYNCHRON LX™ CO2 Alkaline Buffer Reagent
SYNCHRON LX™ ISE Reference Reagent
SYNCHRON LX™ ISE Buffer Reagent
SYNCHRON LX™ AQUA CAL 1, 2, 3
SYNCHRON LX™ Protein Calibrator

3.2 Classification Names

Discrete photometric chemistry analyzer for clinical use; 21 CFR §862.2160
Albumin test system; 21 CFR §862.1035
Creatinine test system; 21 CFR §862.1225
Glucose test system; 21 CFR §862.1345
Phosphorus test sytem; 21 CFR §862.1580
Total Protein test system; 21 CFR §862.1635
Urea Nitrogen test system; 21 CFR §862.1770
Carbon Dioxide test system; 21 CFR §862.1160
Calcium test system; 21 CFR §862.1145
Chloride test system; 21 CFR §862.1170
Potassium test system; 21 CFR §862.1600
Sodium test system; 21 CFR §862.1665
Calibrator; 21 CFR §862.1150

twx: 910-592-1260 • telex: 06-78413

4.0 Predicate Device(s)

Candidate	Predicate	FDA Docket Number
SYNCHRON LX20 System	SYNCHRON CX Systems	K950958
LX20 Albumin Assay	SYNCHRON Systems Albumin	K883181
LX20 Creatinine Assay	SYNCHRON Systems Creatinine	K950958
LX20 Glucose Assay	SYNCHRON Systems Glucose	K950958
LX20 Phosphorus Assay	SYNCHRON Systems Phosphorus	K883181
LX20 Total Protein Assay	SYNCHRON Systems Total Protein	K950958
LX20 Urea Nitrogen Assay	SYNCHRON Systems Urea Nitrogen	K950958
LX20 Carbon Dioxide Assay	SYNCHRON Systems Carbon Dioxide	K950958
LX20 Calcium Assay	SYNCHRON Systems Calcium	K950958
LX20 Chloride Assay	SYNCHRON Systems Chloride	K950958
LX20 Potassium Assay	SYNCHRON Systems Potassium	K950958
LX20 Sodium Assay	SYNCHRON Systems Sodium	K950958
LX AQUA CAL 1,2,3	SYNCHRON Systems Aqueous Cal	K942676
SYNCHRON Protein Cal	SYNCHRON Systems Protein Cal	K952676

5.0 Description

The LX20 Clinical Chemistry System is a fully automated, computer controlled, clinical chemistry analyzer 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, and cerebral spinal fluid (sample type is chemistry dependent). The analyzer operates in conjunction with reagents, calibrators, and controls designed for use with the system. The instrument features bar code identification of samples and reagents. It automatically dilutes samples and delivers them to the reaction cuvette along with reagents and reaction constituents. The system analyzes up to 100 samples per run with up to 41 analytes per sample. Major hardware components include a reagent compartment, sample and reagent cranes, cartridge chemistry section, modular chemistry section, sample carousel and crane, hydropneumatics, electronics, and power supplies.

6.0 Intended Use

The SYNCHRON LX20 Clinical Chemistry System is a fully automated, computer controlled, clinical chemistry analyzer intended for the *in vitro* quantitative measurement of a variety of analytes of clinical interest in biological fluids, such as, serum, plasma, urine, and cerebral spinal fluid (sample type is chemistry dependent).

7.0 Comparison to Predicate(s)

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

Similarities to SYNCHRON CX Systems	
Hardware	separate chemistry analytical unit and operator interface work station as CX Systems
Chemistry Databases	same reaction parameters as for SYNCHRON Systems reagents
Optics and Measurement Types	10 wavelength flash photometer capable of endpoint, rate colorimetric and turbidometric analyses
Electrode Technology	both systems employ conductimetric and oxygen rate electrodes
Differences from SYNCHRON CX Systems	
Operator Interface	LX20 has enhanced operator interface including touch screen and/or pointing device
Features	LX20 has enhanced throughput, reagent capacity, and reaction cuvettes
Menu	LX20 has added Albumin and Phosphorus to the high throughput (MC) portion of the analyzer

8.0 Summary of Performance Data

The data in the Premarket Notification on safety and effectiveness supports a finding of substantial equivalence to *in vitro* diagnostic test systems already in commercial distribution. Equivalence is demonstrated through method comparison and imprecision experiments that relate results obtained from the LX20 Clinical Chemistry System to selected predicate methods.

Serum/Plasma Sample Method Comparison Study Results
LX20 Clinical Chemistry System vs Selected Predicate Methods

Analyte	Slope	Intercept	r	SYNCHRON Systems Predicate
Albumin	0.970	0.070	0.997	Albumin Reagent
Creatinine	1.010	0.04	0.999	Creatinine Reagents
Glucose	0.991	-0.250	0.996	Glucose Reagent
Phosphorus	1.023	0.27	0.996	Phosphorus Reagents
Total Protein	0.962	-0.01	0.993	Total Protein Reagent
Urea Nitrogen	0.949	1.13	0.999	Urea Nitrogen Reagent
Carbon Dioxide	1.015	-0.70	0.992	Carbon Dioxide Reagents
Calcium	0.990	-0.92	0.998	Calcium Reagents
Chloride	0.974	1.04	0.997	Chloride Reagents
Potassium	1.008	-0.01	0.999	Potassium Reagents
Sodium	1.028	-4.22	0.993	Sodium Reagents
Benzodiazepine	Concordance = 100% agreement			Benzodiazepine Reagent
Iron	0.976	9.03	0.997	Iron Reagent
Magnesium	0.971	0.09	0.997	Magnesium Reagent
Phenobarbital	0.976	0.050	0.992	Phenobarbital Reagent
Uric Acid	0.977	-0.02	0.999	Uric Acid Reagent
Lactate Dehydrogenase	1.018	0.20	0.999	LDL Reagent

Estimated Serum/Plasma Within-run Imprecision

Material	Mean	SD	%C.V.	N
Albumin Reagent				
Level 1	2.21 g/dL	0.04	1.9	80
Level 2	4.81 g/dL	0.03	0.6	80
Creatinine Reagent				
Level 1	0.59 mg/dL	0.07	12.2	80
Level 2	8.24 mg/dL	0.18	2.1	80
Glucose Reagent				
Level 1	43.7 mg/dL	1.3	2.9	80
Level 2	397.1 mg/dL	1.7	0.4	80
Phosphorus Reagent				
Level 1	1.80 mg/dL	0.04	2.5	80
Level 2	7.04 mg/dL	0.05	0.7	80

Estimated Serum/Plasma Within-run Imprecision
(continued)

Material	Mean	SD	%C.V.	N
Total Protein				
Level 1	3.54 g/dL	0.06	1.8	80
Level 2	7.52 g/dL	0.05	0.7	80
Urea Nitrogen Reagent				
Level 1	7.7 mg/dL	0.4	5.0	80
Level 2	58.7 mg/dL	0.5	0.9	80
Calcium				
Level 1	7.5 mg/dL	0.08	1.1	80
Level 2	13.5 mg/dL	0.11	0.8	80
Carbon Dioxide				
Level 1	10.58 mmol/L	0.26	2.5	80
Level 2	30.16 mmol/L	0.29	1.0	80
Chloride				
Level 1	81.11 mmol/L	0.47	0.6	80
Level 2	120.53 mmol/L	0.84	0.7	80
Potassium				
Level 1	2.4 mmol/L	0.02	0.9	80
Level 2	7.29 mmol/L	0.04	0.6	80
Sodium				
Level 1	111.1 mmol/L	0.52	0.5	80
Level 2	170.2 mmol/L	1.01	0.6	80
Benzodiazepines				
Cutoff Calibrator	293 mA/min	2.4	0.8	20
High Control	362 mA/min	3.0	0.8	20
Iron				
Level 1	51.2 ug/dL	1.2	2.4	80
Level 2	262.6	2.2	0.9	80
Magnesium				
Level 1	1.12 mg/dL	0.03	3.0	80
Level 2	3.63 mg/dL	0.06	1.5	80
Phenobarbital				
Level 1	9.32 ug/mL	0.22	2.3	80
Level 2	65.86 ug/mL	1.42	2.2	80
Uric Acid				
Level 1	2.42 mg/dL	0.03	1.1	80
Level 2	10.48 mg/dL	0.05	0.5	80
Lactate Dehydrogenase				
Level 1	49.9 IU/L	1.6	3.2	80
Level 2	363.5 IU/L	3.4	1.0	80

Calibrator Material	Stability
AQUA CAL 1, 2, 3	18 months @ 2-8°C
Protein Calibrator	18 months @ 2-8°C

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.