DEC 1 8 2001

510(k) SUMMARY

K014034

1.0 Submitted By:

Annette Hellie
Regulatory Affairs Manager
Beckman Coulter, Inc.
200 S. Kraemer Blvd. W-104
Brea, CA 92822-8000
Telephone: (714) 993-8767
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2.0 Date Submitted

December 6, 2001

3.0 Device Name(s):

3.1 Proprietary Names

SYNCHRON LX® Clinical Systems (ISE Module Chemistries)

3.2 Classification Names

862.1160, pH Rate Measurement, Carbon Dioxide
862.1665 Electrode, Ion Specific, Sodium
862.1600 Electrode, Ion Specific, Potassium
862.1170 Electrode, Ion Specific, Chloride
862.1145 Electrode, Ion Specific, Calcium

4.0 Legally Marketed Device

The SYNCHRON LX® Systems (ISE Module Chemistries) claim substantial equivalence to the SYNCHRON LX® Systems currently in commercial distribution. FDA 510(k) Numbers K965240 (LX20 System) and K011213 (LX20 PRO System).

5.0 Device Description

The SYNCHRON LX® Clinical Systems are manufactured by Beckman Coulter, Inc.

The SYNCHRON LX Clinical 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, and cerebral spinal fluid

(sample type is chemistry dependent). The analyzers operate in conjunction with reagents, calibrators, and controls designed for use with the system. The instruments feature bar code identification of samples and reagents. They automatically dilute samples and deliver them to the associated reaction vessel for each system module (cuvette, cup, or ISE flowcell) along with reagents and reaction constituents. The systems analyze 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.

The LX20 PRO is differentiated from the standard LX20 system with the following hardware: LPIA (Large Particle Immunoassay) Module and TS-CTS (Thick Stopper-Closed Tube Sampling) Module

The fixed menu ISE flow cell module is contained in the modular chemistry area. The ISE flow cell contains ISE electrodes for the measurement of Sodium (NA), Potassium (K), Chloride (CL), carbon dioxide (CO2), and Calcium (CALC).

6.0 Intended Use

The SYNCHRON LX Clinical 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, and cerebral spinal fluid (sample type is chemistry dependant).

7.0 Comparison to the Predicate (Description of the Modification to the Legally Marketed Device)

The modified SYNCHRON LX Systems utilize a new ISE (Ion Selective Electrode) sample volume of 40 µL. The prior sample volume was 62µL. These SYNCHRON LX ISE methods include:

Sodium (NA)
Potassium (K)
Chloride (Cl)
Carbon Dioxide (CO2)
Calcium (CALC)

8.0 Summary of Performance Data

Performance data from validation testing supports equivalency.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

Ms. Annette Hellie
Regulatory Affairs Manager
Beckman Coulter, Inc.
200 S. Kraemer Blvd
M/S W-104
Box 8000
Brea, CA 92822-8000

DEC 1 3 2001

Re: k014034
Trade/Device Name: Synchron LX® Systems Carbon Dioxide (CO2) Assay;
Synchron LX® Systems Calcium (CALC) Assay;
Synchron LX® Systems Chloride (CL) Assay;
Synchron LX® Systems Potassium (K) Assay;
Synchron LX® Systems Sodium (NA) Assay;
Regulation Number: 21 CFR 862.1160; 21 CFR 862.1665; 21 CFR.1600;
21 CFR 862.1170; 21 CFR 862.1145
Regulation Name: Bicarbonate/carbon dioxide test system; Sodium test system;
Potassium test system; Chloride test system; Calcium test system
Regulatory Class: Class II; Class II; Class II; Class II; Class II
Product Code: JFL; JGS; CGM; CGZ; JFP
Dated: December 7, 2001
Received: December 7, 2001

Dear Ms. Hellie:

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 the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. 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 Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

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 Part 801 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-__. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained 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,

Steven Gutman

Steven I. Gutman, M.D., M.B.A.
Director
Division of Clinical Laboratory Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K014034

Device Name:

SYNCHRON LX® Systems Carbon Dioxide (CO2) Assay

Indications for Use:

SYNCHRON LX ISE Electrolyte Buffer Reagent, SYNCHRON LX ISE Electrolyte Reference Reagent, and CO_2 Alkaline Buffer and Acid Reagent, in conjunction with SYNCHRON LX AQUA CAL 1 and 3, are intended for quantitative determination of carbon dioxide (CO_2) in serum or plasma on SYNCHRON LX Systems.

Clinical Significance:

A bicarbonate/carbon dioxide test system is a device intended to measure bicarbonate/carbon dioxide in plasma, serum, and whole blood. Bicarbonate/carbon dioxide measurements are used in the diagnosis and treatment of numerous potentially serious disorders associated with changes in body acid-base balance.

(Division Sign-Off)
Division of Clinical Laboratory Devices
510(k) Number K014034

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use Y OR Over-the-Counter Use _____
(per 21 CFR 801.109) Optional Format 1-2-96

510(k) Number (if known): K014034

Device Name:

SYNCHRON LX® Systems Calcium (CALC) Assay

Indications for Use:

SYNCHRON LX ISE Electrolyte Buffer Reagent and SYNCHRON LX ISE Electrolyte Reference Reagent, in conjunction with SYNCHRON LX AQUA CAL 1 and 2, are intended for quantitative determination of calcium (CALC) in serum, plasma or urine on SYNCHRON LX Systems.

Clinical Significance:

A calcium test system is a device intended to measure the total calcium level in serum. 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).

for Jean Cooper

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Division of Clinical Laboratory Devices
510(k) Number K014034

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use X OR Over-the-Counter Use _____
(per 21 CFR 801.109) Optional Format 1-2-96

510(k) Number (if known): K014034

Device Name:

SYNCHRON LX® Systems Chloride (CL) Assay

Indications for Use:

SYNCHRON LX ISE Electrolyte Buffer Reagent and SYNCHRON LX ISE Electrolyte Reference Reagent, in conjunction with SYNCHRON LX AQUA CAL 1 and 2, are intended for quantitative determination of chloride (CL) in serum, plasma, urine or cerebrospinal fluid (CSF) on SYNCHRON LX Systems.

Clinical Significance:

A chloride test system is a device intended to measure the level of chloride in plasma, serum, sweat, and urine. Chloride measurements are used in the diagnosis and treatment of electrolyte and metabolic disorders such as cystic fibrosis and diabetic acidosis.

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Prescription Use X OR Over-the-Counter Use _____
(per 21 CFR 801.109) Optional Format 1-2-96

510(k) Number (if known): K014034

Device Name:

SYNCHRON LX® Systems Potassium (K) Assay

Indications for Use:

SYNCHRON LX ISE Electrolyte Buffer Reagent and SYNCHRON LX ISE Electrolyte Reference Reagent, in conjunction with SYNCHRON LX AQUA CAL 1, 2 and 3, are intended for the quantitative determination of potassium (K) in serum, plasma or urine on the SYNCHRON LX System.

Clinical Significance:

A potassium test system is a device intended to measure potassium in serum, plasma, and urine. Measurements obtained by this device are used to monitor electrolyte balance in the diagnosis and treatment of diseases conditions characterized by low or high blood potassium levels.

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Prescription Use X (per 21 CFR 801.109) OR Over-the-Counter Use _____ Optional Format 1-2-96

510(k) Number (if known): K014034

Device Name:

SYNCHRON LX® Systems Sodium (NA) Assay

Indications for Use:

SYNCHRON LX ISE Electrolyte Buffer Reagent and SYNCHRON LX ISE Electrolyte Reference Reagent, in conjunction with SYNCHRON LX AQUA CAL 1, 2 and 3, are intended for the quantitative determination of sodium (NA) in serum, plasma or urine on the SYNCHRON LX System.

Clinical Significance:

A sodium test system is a device intended to measure sodium in serum, plasma, and urine. Measurements obtained by this device are used in the diagnosis and treatment of aldosteronism (excessive secretion of the hormone aldosterone), diabetes insipidus (chronic excretion of large amounts of dilute urine, accompanied by extreme thirst), adrenal hypertension, Addison's disease (caused by destruction of the adrenal glands), dehydration, inappropriate antidiuretic hormone secretion, or other diseases involving electrolyte imbalance.

for Jean Cooper
(Division Sign-Off)
Division of Clinical Laboratory Devices
510(k) Number K014039

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-the-Counter Use _____
(per 21 CFR 801.109) Optional Format 1-2-96