FEB 27 2006

K060256

510(k) Summary
UniCel® DxC 600i System

1.0 Submitted By:

Mary Beth Tang
Staff Regulatory Affairs Specialist
Beckman Coulter, Inc.
200 S. Kraemer Blvd. W-110
Brea, CA 92822-8000
Telephone: (714) 961-3777
FAX: (714) 961-4123

2.0 Date Submitted

January 31, 2006

3.0 Device Name(s):

3.1 Proprietary Names:
UniCel® DxC 600i Synchron® Access® Clinical System

3.2 Classification Names:
Discrete photometric chemistry analyzer for clinical use [862.2160]

4.0 Legally Marketed Device

The UniCel DxC 600i System claims substantial equivalence to the SYNCHRON LXi 725 System (Docket Number K023049) currently in commercial distribution.

5.0 Device Description

The UniCel DxC 600i System combines the UniCel DxC 600 analyzer and Access 2 Immunoassay analyzer into a single instrument presentation. Samples are loaded from a single point of entry through the Closed Tube Aliquoter (CTA) connector unit. The CTA functions as a sample processing manager by aliquotting and routing samples to the Access 2 and/or DxC 600 modules according to programming requirements. The DxC 600 and Access 2 systems then deliver samples to the appropriate reaction vessel along with reagents and reaction constituents. The DxC 600-based console functions as the main user interface for managing routine operations such as sample programming, results management, and QC functions.

The DxC 600i system provides analysis of up to 94 analytes per sample, operating in conjunction with the existing reagents, calibrators, and controls designed for use with Beckman Coulter's SYNCHRON and Access instrument families. The instrument features bar code identification of samples and reagents, Closed Tube Sampling (CTS), and obstruction detection and correction capability. DxC 600i system components include the DxC 600 analyzer and console, the CTA module, and the Access 2 module and console. The subsystem hardware components for the analytical units include reagent storage compartments, sample and reagent delivery systems, cap piercing assemblies, sample carousels and cranes, hydropneumatics, fluidics, photometric detectors, electronics, and power supplies.

The DxC 600i System incorporates the following upgrades to the LXi 725 System:

1. General Chemistry Module

The UniCel DxC 600 System (previously reviewed/cleared under K042291) replaces the LX20 PRO System as the general chemistry module and main system console. The DxC 600 implements a dual-carousel refrigeration unit to increase reagent cartridge storage capacity and expand the onboard test menu. The DxC 600 offers robustness and feature enhancements over the LX20 PRO, and has a smaller instrument footprint to reduce the overall size of the "i" configuration.

2. Hardware Modifications

The CTA unit upgrades address parts obsolescence and performance quality issues related to the barcode reader, syringe module and pump. The Access 2 module has updated electronic components to support the obstruction detection feature. There are also instrument cover changes to match the DxC 600 design.

3. Software Modifications

The DxC 600i System utilizes DxC operating software version 1.4. Version 1.4 contains the information necessary to configure, order, and report results for Access 2 tests and an updated chemistry database. The Access 2 module operating software is updated to achieve alignment with stand-alone Access 2 operating software. The CTA module software is updated to implement robustness improvements and new features.

6.0 Intended Use

The UniCel® DxC 600i System combines the UniCel® DxC 600 analyzer and the Access® 2 analyzer into a single instrument presentation. Samples are loaded from a single point of entry through a Closed Tube Aliquoter (CTA) unit. The CTA functions as a sample processing manager by aliquotting and routing samples to the Access 2 and/or UniCel DxC 600 analyzer according to programming requirements.

The UniCel DxC 600 Synchron® Clinical 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, or cerebrospinal fluid, (sample type is chemistry dependent).

The Access 2 Immunoassay Analyzer is a microcomputer controlled, random access instrument. The analyzer performs enzyme immunoassays utilizing paramagnetic particle solid phase and chemiluminescent detection. The Access 2 Analyzer is intended for the in vitro determination 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 the Predicate

The SYNCHRON LXi 725 system has been upgraded to a DxC 600i System through 1) replacement of the LX20 PRO module with a modified DxC 600 PRO analyzer, 2) modified CTA and Access 2 hardware elements and instrument covers, and, 3) software updates to the DxC 600, Access 2, and CTA modules. There is also a name change to UniCel DxC 600i System.

8.0 Summary of Performance Data

Performance data from validation testing supports equivalency.

Section 1: ADMINISTRATIVE INFORMATION

1.0 Submitted By:

Beckman Coulter, Inc.
200 S. Kraemer Blvd. W-110
Brea, CA 92822-8000

Primary Contact:
Mary Beth Tang, Staff Regulatory Affairs Specialist
Telephone: (714) 961-3777
FAX: (714) 961-4123
E-mail: mtang@beckman.com

Secondary Contact:
Annette Hellie, Staff Regulatory Affairs Specialist
Telephone: (714) 993-8767
FAX: (714) 961-4123

2.0 Sponsor Address/FDA Registration Number

Beckman Coulter, Inc.
200 S. Kraemer Blvd. W-110
Brea, CA 92822-8000
Establishment Registration No. 2050012

3.0 Product Name/Classification Name and Number

Proprietary Names

UniCel® DxC 600i Synchron® Access® Clinical System

Classification Names

Discrete photometric chemistry analyzer for clinical use [862.2160]

4.0 Device Classification

FDA has classified clinical chemistry test systems of this type into Class I (reserved)

5.0 Section 514 Compliance

This Special 510(k): Device Modification submission is prepared pursuant to the FDA publication: The New 510(k) Paradigm: Alternate Approaches to Demonstrating Substantial Equivalence in Premarket Notifications – Issue Date: March 20, 1998.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

FEB 2 7 2006

Ms. Mary Beth Tang
Staff Regulatory Affairs Specialist
Beckman Coulter, Inc.
200 S. Kraemer Blvd. W-110
Brea, CA 92822-8000

Re: k060256
Trade/Device Name: UniCel® DxC 600i Synchron® Access® Clinical System
Regulation Number: 21 CFR§862.1345
Regulation Name: Glucose test system
Regulatory Class: Class II
Product Code: CFR, JFP, CHL, CGZ, CEM, JGS, CDQ, DCK, JIY, LCD, DFT, JXM, LCP, JLW, JHI, JMG, CGN, JJE
Dated: January 31, 2006
Received: February 1, 2006

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.

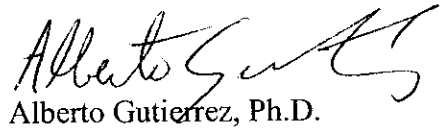
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish 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 (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): K060256

Device Name: UniCel® DxC 600i Synchron® Access® Clinical System

Indications for Use:

The UniCel® DxC 600i System combines the UniCel® DxC 600 analyzer and the Access® 2 analyzer into a single instrument presentation. Samples are loaded from a single point of entry through a Closed Tube Aliquoter (CTA) unit. The CTA functions as a sample processing manager by aliquotting and routing samples to the Access 2 and/or UniCel DxC 600 analyzer according to programming requirements.

The UniCel DxC 600 Synchron® Clinical 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, or cerebrospinal fluid, (sample type is chemistry dependent).

The Access 2 Immunoassay Analyzer is a microcomputer controlled, random access instrument. The analyzer performs enzyme immunoassays utilizing paramagnetic particle solid phase and chemiluminescent detection. The Access 2 Analyzer is intended for the in vitro determination 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).

Prescription Use __X__ AND/OR Over-the-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

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

Carol Benson

Division of
Device Evaluation

510(k) K060256

Indications for Use – Submitted Analytes

510(k) Number (if known): K965240, K042291, K060256

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.

510(k) Number (if known): K965240, K042291, K060256

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.

510(k) Number (if known): K965240, K042291, K060256

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).

Carol Benson

K060256

Analyte Indications for Use (cont.)

510(k) Number (if known): K965240, K042291, K060256

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 measurements are used in the diagnosis and treatment of electrolyte and metabolic disorders.

510(k) Number (if known): K965240, K042291, K060256

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 treatment of hypokalemia, hyperkalemia, renal failure, Addison's disease or other diseases involving electrolyte imbalance.

510(k) Number (if known): K965240, K042291, K060256

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.

Carol C Benson

K060256

Analyte Indications for Use (cont.)

510(k) Number (if known): K965240, K042291, K060256

Device Name: SYNCHRON® Systems AQUA CAL 1, 2 and 3

Indications for Use:

The Beckman Coulter AQUA CAL 1, 2, and 3 are intended for use on SYNCHRON LX® and UniCel® DxC Systems for the calibration of Sodium, Potassium, Chloride, Urea Nitrogen, Urea, Glucose, Creatinine, Calcium, Carbon Dioxide, and Phosphorus.

510(k) Number (if known): K883181, K060256

Device Name: SYNCHRON® Systems Blood Urea Nitrogen (BUN) Reagent

Indications for Use:

BUN reagent, when used in conjunction with SYNCHRON LX® System(s), UniCel® DxC 600/800 System(s) and SYNCHRON® Systems Multi Calibrator, is intended for the quantitative determination of Urea Nitrogen concentration in human serum, plasma or urine.

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

510(k) Number (if known): K010597, K060256

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.

Carol Benson

K060256

Analyte Indications for Use (cont.)

510(k) Number (if known): K960485, K060256

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.

510(k) Number (if known): K955644, K060256

Device Name: SYNCHRON® Systems Gentamicin (GEN) Reagent

Indications for Use:

GEN reagent, when used in conjunction with SYNCHRON LX® System(s), UniCel® DxC 600/800 System(s) and SYNCHRON® Systems Drug Calibrator 3 Plus, is intended for quantitative determination of Gentamicin concentration in human serum or plasma.

Gentamicin is an antibiotic used to treat serious gram-negative bacterial infections. Gentamicin therapy is monitored for effectiveness of the dose and possible nephrotoxicity.

510(k) Number (if known): K965108, K060256

Device Name: SYNCHRON® Systems Immunoglobulin M (IGM) Reagent

Indications for Use:

Ig-M reagent, when used in conjunction with SYNCHRON LX® System(s), UniCel® DxC 600/800 System(s) and SYNCHRON® Systems CAL 1, is intended for quantitative determination of Immunoglobulin M concentration in human serum or plasma.

Measurements of immunoglobulin M are used in the diagnosis and treatment of immune deficiency states, protein-losing conditions, Waldenstrom`s macroglobinemia, chronic infections, and liver disease.

Carol Benson

K060256

Analyte Indications for Use (cont.)

510(k) Number (if known): K043556, K060256

Device Name: SYNCHRON® Systems Benzodiazepine (BNZG) Reagent

Indications for Use:

BNZG reagent, when used in conjunction with SYNCHRON LX® System(s), UniCel® DxC 600/800 System(s) 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 BNZG 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.Error! Reference source not found.Error! Reference source not found.

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

510(k) Number (if known): K042459, K060256

Device Name: SYNCHRON® Systems Hemoglobin A1c (HbA1c2) Reagent

Indications for Use:

The Hemoglobin A1c2 (HbA1c2) reagent, when used in conjunction with SYNCHRON LX® System(s), UniCel® DxC 600/800 System(s) and SYNCHRON® Systems HbA1c2 Calibrators, is intended for the quantitative determination of hemoglobin A1c (HbA1c2) concentration as a percentage of total hemoglobin in human whole blood.

Measurement of hemoglobin A1c is accepted as a method to measure long-term glucose control in patients with diabetes mellitus (a chronic disorder associated with disturbances in carbohydrate, fat, and protein metabolism and characterized by hyperglycemia). Determination of hemoglobin A1c provides an important diagnostic tool for monitoring the efficiency of dietary control and therapy during treatment of diabetes mellitus.

510(k) Number (if known): K042281, K060256

Device Name: Access® HYPERsensitive hTSH Assay

Indications for Use:

The Access HYPERsensitive hTSH Assay provides in vitro quantitative measurement of the human thyroid-stimulating hormone (hTSH) in human serum or plasma. The Access HYPERsensitive hTSH Assay is indicated for use with patients where an assessment of their thyroid status is desired. This assay is capable of providing 3rd generation (HYPERsensitive hTSH) and / or 2nd generation (Fast hTSH) results.

Carol Benson

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Analyte Indications for Use (cont.)

510(k) Number (if known): K023480, K060256

Device Name: Access® Total βhCG Assay

Indications for Use:

The Access Total βhCG assay provides in vitro quantitative determination of total βhCG levels in human serum and plasma. The Access Total βhCG assay is indicated for use with patients where an early detection of pregnancy status is desired.

510(k) Number (if known): K955434, K060256

Device Name: Access® Ferritin Assay

Indications for Use:

The Access Ferritin assay is a paramagnetic particle, chemiluminescent immunoassay for the quantitative determination of ferritin levels in human serum and plasma (heparin) using the Access Immunoassay Systems.

510(k) Number (if known): K052082, K060256

Device Name: Access® Folate Assay

Indications for Use:

The Access Folate assay is a paramagnetic particle, chemiluminescent immunoassay for the quantitative determination of folic acid levels in human serum, plasma (heparin) or red blood cells using the Access Immunoassay Systems.

Prescription Use __X__ AND/OR Over-the-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

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