DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
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December 16, 2016

BECKMAN COULTER INC.
GERALDINE FUENTESPINA
MANAGER, REGULATORY AFFAIRS
250 S. KRAEMER BLVD. MAILS STOP E1.SE.01
BREA, CA 92821

Re: K161837
Trade/Device Name: ISE Reagents, Glucose, and CRP Latex on the DxC 700 AU Clinical Analyzer
Regulation Number: 21 CFR 862.1665
Regulation Name: Sodium Test System
Regulatory Class: II
Product Code: JGS, CEM, CGZ, CFR, NQD, JJE
Dated: December 2, 2016
Received: December 5, 2016

Dear Geraldine Fuentespina:

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. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to 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.

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); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); 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.

If you desire specific advice for your device on our labeling regulations (21 CFR Parts 801 and 809), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Courtney H. Lias -S

Courtney H. Lias, Ph.D.
Director
Division of Chemistry and Toxicology Devices
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and Radiological Health
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K161837

Device Name
DxC 700 AU Clinical Chemistry Analyzer, CRP Latex, Glucose, ISE Reagents

Indications for Use *(Describe)*
The Beckman Coulter DxC 700 AU Clinical Chemistry Analyzer is an automated chemistry analyzer that measures analytes in samples, in combination with appropriate reagents, calibrators, quality control (QC) material and other accessories. This system is for in vitro diagnostic use only. Applications include colorimetric, latex agglutination, and ion selective electrode.

The Glucose test system is for the quantitative measurement of glucose in human serum, plasma, urine and cerebrospinal fluid on Beckman Coulter AU analyzers. Glucose measurements are used in the diagnosis and treatment of carbohydrate metabolism disorders including diabetes mellitus, neonatal hypoglycemnia, and idiopathic hypoglycemia, and of pancreatic islet cell carcinoma.

System reagent for the quantitative determination of C-Reactive Protein in human serum and plasma on Beckman Coulter AU Analyzers. Measurement of CRP is useful for the detection and evaluation of infection, tissue injury, inflammatory disorders and associated diseases. Measurements may also be useful as an aid in the identification of individuals at risk for future cardiovascular disease. High sensitivity CRP (hsCRP) measurements, when used in conjunction with traditional clinical laboratory evaluation of acute coronary syndromes, may be useful as an independent marker of prognosis for recurrent events, in patients with stable coronary disease or acute coronary syndromes.

Reagents for the quantitative determination of Sodium, Potassium and Chloride concentrations in human serum, plasma and urine on the Beckman Coulter ISE modules.

The sodium test system is intended for the quantitative measurement 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.

The potassium test system is intended for the quantitative measurement of potassium in serum, plasma, and urine. Measurements obtained by this device are used to monitor electrolyte balance in the diagnosis and treatment of disease conditions characterized by low or high blood potassium levels.

The chloride test system is intended for the quantitative measurement of the level of chloride in plasma, serum, and urine. Chloride measurements are used in the diagnosis and treatment of electrolyte and metabolic disorders such as cystic fibrosis and diabetic acidosis.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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This summary of the 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

1.0 Submitted By

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2.0 Date of Preparation

14 December 2016

3.0 Device Name(s)

3.1 ISE Reagent

Proprietary Name: ISE Reagents
Common Name: ISE Reagents
Class: 2
Classification Name/Regulation Number/Product Code:
Sodium test system 21 CFR § 862.1665 [JGS]
Potassium test system 21 CFR § 862.1600 [CEM]
Chloride test system 21 CFR § 862.1170 [CGZ]

3.2 Glucose

Proprietary Name: Glucose
Common Name: Glucose
Class: 2
Classification Name: Glucose test system
Regulation Number: 21 CFR § 862.1345
Product Code: CFR

3.3 CRP Latex

Proprietary Name: CRP Latex
Common Name: CRP Latex
Class: 2
Classification Name: C-reactive protein immunological test system
Regulation Number: 21 CFR § 866.5270
Product Code: NQD

3.4 DxC 700 AU Clinical Chemistry Analyzer

Proprietary Name: DxC 700 AU Clinical Chemistry Analyzer
Common Name: DxC 700 AU
Class: 1
Classification Name: Discrete photometric chemistry analyzer for clinical use
Regulation Number: 21 CFR § 862.2160
Product Code: JJE

4.0 Predicate Devices

Candidate(s)	Predicate	Manufacturer
ISE Reagents : Sodium and Chloride	ISE Reagents : Potassium, Sodium and Chloride (K003721)	Beckman Coulter, Inc.
ISE Reagents : Potassium	ISE Reagents : Potassium (K112412)	Beckman Coulter, Inc.
Glucose	Glucose (K112412)	Beckman Coulter, Inc.
CRP Latex	OLYMPUS CRP Latex Immunoturbidimetric Reagent (K051564)	Beckman Coulter, Inc.
DxC 700 AU Clinical Chemistry Analyzer	AU5800 Clinical Chemistry Analyzer (K112412)	Beckman Coulter, Inc.

5.0 Device Description

5.1 ISE Reagents

The ISE module for Na^+, K^+, and Cl^- employs crown ether membrane electrodes for sodium and potassium and a molecular oriented PVC membrane for chloride that are specific for each ion of interest in the sample. An electrical potential is developed according to the Nernst Equation for a specific ion. When compared to the Internal Reference Solution, this electrical potential is translated into voltage and then into the ion concentration of the sample.

Reactive Ingredients: ISE Buffer (Triethanolamine), Mid-Standard (Na, K, Cl), Reference (Potassium Chloride), High Serum Standard (Na, K, Cl), Low Serum Standard (Na, K, Cl), High/Low Urine Standard (Na, K, Cl), Internal Reference Solution (Potassium Chloride, Silver Chloride), and Na^+/K^+ Selectivity Check Solution (Na, K).

5.2 Glucose

In this Beckman Coulter procedure, glucose is phosphorylated by hexokinase (HK) in the presence of adenosine triphosphate (ATP) and magnesium ions to produce glucose-6-phosphate (G-6-P) and adenosine diphosphate (ADP). Glucose-6-phosphate dehydrogenase (G6P-DH) specifically oxidizes G-6-P to 6-phosphogluconate with the concurrent reduction of nicotinamide adenine dinucleotide (NAD+) to nicotinamide adenine dinucleotide, reduced (NADH).

For the AU400/AU640/AU600 the change in absorbance at 340/380 nm is proportional to the amount of glucose present in the sample. For the AU5800/AU5400/AU2700/AU680/AU480/DxC 700 AU the change in absorbance at 340/660 nm is proportional to the amount of glucose present in the sample.

Reactive Ingredients: PIPES- buffer (pH 7.6), NAD^+, Hexokinase, ATP, Mg^{2+}, G6P-DH

5.3 CRP Latex

The CRP Latex reagent is an in vitro diagnostic device that consists of ready to use buffer and latex particles coated with rabbit anti-CRP antibodies. Depending on the application used (different instrument settings), two measuring ranges are available: Normal application (CRP Concentrations ranging between 1.0-480 mg/L) and Highly Sensitive (Cardiac/ Neonatal) Application- (CRP concentrations ranging between 0.2- 80mg/L).

Reactive Ingredients: Glycine buffer, Latex coated with anti-CRP Antibodies.

5.4 DxC 700 AU Clinical Chemistry Analyzer

The Beckman Coulter DxC 700 AU Clinical Chemistry Analyzer carries out automated analysis of serum, plasma, urine samples and other body fluids and automatically generates results. The device is an automated chemistry analyzer that measures analytes in samples, in combination with appropriate reagents, calibrators, quality control (QC) material and other accessories. This system is for in vitro diagnostic use only. Applications include colorimetric, latex agglutination and ion selective electrode. Electrolyte measurement is performed using a single cell Ion Selective Electrode (ISE) which is also common among the other members of the AU family.

6.0 Indications for Use

6.1 ISE Reagents (Sodium, Potassium and Chloride)

Reagents for the quantitative determination of Sodium, Potassium and Chloride concentrations in human serum, plasma and urine on the Beckman Coulter ISE modules.

The sodium test system is intended for the quantitative measurement 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.

The potassium test system is intended for the quantitative measurement of potassium in serum, plasma, and urine. Measurements obtained by this device

are used to monitor electrolyte balance in the diagnosis and treatment of disease conditions characterized by low or high blood potassium levels.

The chloride test system is intended for the quantitative measurement the level of chloride in plasma, serum, and urine. Chloride measurements are used in the diagnosis and treatment of electrolyte and metabolic disorders such as cystic fibrosis and diabetic acidosis.

6.2 Glucose

The Glucose test system is for the quantitative measurement of glucose in human serum, plasma, urine and cerebrospinal fluid on Beckman Coulter AU analyzers.

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

6.3 CRP Latex

System reagent for the quantitative determination of C-Reactive Protein in human serum and plasma on Beckman Coulter AU Analyzers. Measurement of CRP is useful for the detection and evaluation of infection, tissue injury, inflammatory disorders and associated diseases. Measurements may also be useful as an aid in the identification of individuals at risk for future cardiovascular disease. High sensitivity CRP (hsCRP) measurements, when used in conjunction with traditional clinical laboratory evaluation of acute coronary syndromes, may be useful as an independent marker of prognosis for recurrent events, in patients with stable coronary disease or acute coronary syndromes.

6.4 DxC 700 AU Clinical Chemistry Analyzer

The Beckman Coulter DxC 700 AU Clinical Chemistry Analyzer is an automated chemistry analyzer that measures analytes in samples, in combination with appropriate reagents, calibrators, quality control (QC) material and other accessories. This system is for in vitro diagnostic use only. Applications include colorimetric, latex agglutination, and ion selective electrode.

7.0 Comparison to the Predicate

The DxC 700 AU Clinical Chemistry System is a family member of the AU series of analyzers, including the AU5800 (K112412) to which the substantial equivalence comparison is claimed. The devices have same / similar design and modes of operation. The key features are summarized in the following tables:

7.1 ISE Reagents (Sodium & Chloride) Predicate Device Comparison Table

Feature	Predicate Device: ISE Reagents – Sodium and Chloride (K003721)	Proposed Device: ISE Reagents - Sodium and Chloride
Item Number	AUH1011, AUH1012, AUH1013, AUH1014, AUH1015, AUH1016, AUH1017, AUH1018	Same
Intended Use	Reagent for the quantitative determination of Sodium, Potassium and Chloride concentrations in human serum and urine on the Beckman Coulter ISE modules.	Same
Measurement	Quantitative	Same
Instrument Required	AU400/400^{e}, AU600/640/640^{e}, AU800,AU1000, AU5200 and AU2700 Beckman Coulter Analyzers	AU400/400^{e}/480, AU600/640/640^{e}/680, AU2700/5400/AU5800 and DxC 700 AU Beckman Coulter Analyzers.
Methodology	Indirect ISE	Same
Reagent form and storage	Liquid, on-board storage	Same
Specimen Type	Serum, plasma and urine	Same
Calibrator	AUH1014 Low Serum Standard AUH1015 High Serum Standard AUH1016 High/Low Urine Standard	Same
Calibration Stability	Calibrate daily.	Same
Reagent stability	AUH1011, AUH1012, and AUH1013 are stable for 90 days when opened and stored in the ISE reagent compartment of the analyzer. After opening AUH1014, AUH1015, AUH1016, and AUH1018 may be stored at 2 – 25°C for up to 90 days, provided the cap is replaced immediately after each use. After opening, AUH1017 may be stored at 15 - 25°C for up to 90 days.	Same

Feature	Predicate Device: ISE Reagents – Sodium and Chloride (K003721)	Proposed Device: ISE Reagents - Sodium and Chloride
Analytic Range	Serum Na^+ 50 – 200 mEq/L Cl^- 50 – 200 mEq/L Urine Na^+ 10 – 400 mEq/LL Cl^- 15 – 400 mEq/L	Same

7.2 ISE Reagents (Potassium) Predicate Device Comparison Table

Feature	Predicate Device: ISE Reagents - Potassium (K112412)	Proposed Device: ISE Reagents – Potassium
Item Number	AUH1011, AUH1012, AUH1013, AUH1014, AUH1015, AUH1016, AUH1017, AUH1018	Same
Intended Use	Reagent for the quantitative determination of Sodium, Potassium and Chloride concentrations in human serum and urine on the Beckman Coulter ISE modules.	Same
Measurement	Quantitative	Same
Instrument Required	AU400/400^e/480, AU600/640/640^e/680 and AU2700/5400/AU5800 Beckman Coulter Analyzers	AU400/400^e/480, AU600/640/640^e/680, AU2700/5400/AU5800 and DxC 700 AU Beckman Coulter Analyzers.
Methodology	Indirect ISE	Same
Reagent form and storage	Liquid, on-board storage	Same
Specimen Type	Serum, plasma and urine	Same
Calibrator	AUH1014 Low Serum Standard AUH1015 High Serum Standard AUH1016 High/Low Urine Standard	Same
Calibration Stability	Calibrate daily.	Same
Reagent stability	AUH1011, AUH1012, and AUH1013 are stable for 90 days when opened and stored in the ISE reagent compartment of the analyzer. After opening AUH1014, AUH1015, AUH1016, and AUH1018 may be stored at 2 – 25°C for up to 90 days, provided the cap is replaced immediately after each use. After opening, AUH1017 may be stored at 15 - 25°C for up to 90 days.	Same

Feature	Predicate Device: ISE Reagents - Potassium (K112412)	Proposed Device: ISE Reagents – Potassium
Analytic Range	Serum K^+ 1.0 – 10.0 mEq/L Urine K^+ 2.0 – 200.0 mEq/L	Same

7.3 Glucose Predicate Device Comparison Table

Feature	Predicate Device: Glucose (K112412)	Proposed Device: Glucose
Item Number	Glucose (OSR6121, OSR6221, OSR6621)	Same
Intended Use	System reagent for the quantitative determination of Glucose in human serum, plasma, urine and cerebrospinal fluid on Beckman Coulter AU analyzers.	Same
Measurement	Quantitative	Same
Instrument Required	AU400/400^e/480, AU600/640/640^e/680 and AU2700/5400/AU5800 Beckman Coulter Analyzers	AU400/400^e/480, AU600/640/640^e/680, AU2700/5400/AU5800 and DxC 700 AU Beckman Coulter Analyzers.
Methodology	Photometric	Same
Reagent form and storage	Liquid, on-board storage	Same
Specimen Type	Serum, plasma, urine and cerebrospinal fluid	Same
Calibrator	Chemistry Calibrator (Cat # DR0070) Urine Calibrator (Cat # DR0090)	Same
Calibration Stability	30 days	Same
Onboard Stability	30 days refrigerated	Same
Analytic Range	Serum, plasma and CSF: 10 - 800 mg/dL Urine: 10 - 700 mg/dL	Same

7.4 CRP Predicate Device Comparison Table

Feature		Predicate Device: CRP Latex (K051564)	Proposed Device: CRP Latex
Item Number		CRP Latex (OSR6199)	Same
Intended Use		*Olympus* System Reagent *and calibrators* for the quantitative determination of C-Reactive Protein in human serum and plasma on *OLYMPUS* Analyzers. Measurement of CRP is useful for the detection and evaluation of infection, tissue injury, inflammatory disorders and associated diseases. Measurements may also be used as an aid in the identification of individuals at risk *of* future cardiovascular disease. High sensitivity CRP (hsCRP) measurements, when used in conjunction with traditional clinical laboratory evaluation of acute coronary syndromes, maybe useful as an independent marker of prognosis for recurrent events, in patients with stable coronary disease or acute coronary syndromes.	Same System reagent for the quantitative determination of C-Reactive Protein in human serum and plasma on *Beckman Coulter AU* Analyzers. Measurement of CRP is useful for the detection and evaluation of infection, tissue injury, inflammatory disorders and associated diseases. Measurements may also be useful as an aid in the identification of individuals at risk *for* future cardiovascular disease. High sensitivity CRP (hsCRP) measurements, when used in conjunction with traditional clinical laboratory evaluation of acute coronary syndromes, may be useful as an independent marker of prognosis for recurrent events, in patients with stable coronary disease or acute coronary syndromes.
Measurement		Quantitative	Same
Instrument Required		AU400/400^{e}/480, AU600/640/640^{e}/680 and AU2700/5400/AU5800 Beckman Coulter Analyzers	AU400/400^{e}/480, AU600/640/640^{e}/680, AU2700/5400/AU5800 and DxC 700 AU Beckman Coulter Analyzers.
Methodology		Latex enhanced Immunoturbidimetric	Same
Antibody		Rabbit Anti-CRP Antibodies	Same
Reagent form and storage		Liquid, on-board storage	Same
Specimen Type		Serum and plasma	Same
Calibrator		CRP Latex Highly Sensitive Calibrator (Cat # ODC0027) for the Highly Sensitive (Cardiac / Neonatal) Application.	Same
Calibration Stability		30 days refrigerated	90 days refrigerated
Onboard Stability		30 days refrigerated	90 days refrigerated
Analytic Range	Highly Sensitive	0.2 - 160 mg/L	0.2 to 80 mg/L

7.5 AU5800 versus the DxC 700 AU Predicate Device Comparison Table

Feature	Predicate Device: AU5800 Clinical Chemistry Analyzer (K112412)	Proposed Device: DxC 700 AU Clinical Chemistry Analyzer
Intended Use:	The Beckman Coulter AU5800 Clinical Chemistry Analyzer is an automated chemistry analyzer that measures analytes in samples, in combination with appropriate reagents, calibrators, quality control (QC) material and other accessories. This system is for in vitro diagnostic use only. Applications include colorimetric, turbidimetric, latex agglutination, homogeneous enzyme immunoassay, and ion selective electrode.	Similar to predicate. The Beckman Coulter DxC 700 AU Clinical Chemistry Analyzer is an automated chemistry analyzer that measures analytes in samples, in combination with appropriate reagents, calibrators, quality control (QC) material and other accessories. This system is for in vitro diagnostic use only. Applications include colorimetric, latex agglutination and ion selective electrode.
Classification:	Analyzer, chemistry (photometric, discrete), for clinical use has been classified as Class I, JJE by the Clinical Chemistry and Clinical Toxicology Devices Panel, (21 CFR 862.2160).	Identical to predicate.
Sample Handling		
Sample Containers	10 sample tubes on a Rack	Identical to predicate.
Sample Volume	1.0 to 17.0 µL	1.0 to 25.0 µL
Sample Types	Serum, urine, CSF and Plasma	Identical to predicate.
Sample Input	Sample Racks	Sample Rack, STAT Table, Direct-line Sample Aspiration (For Automation Connections)
Single Sample Replicate Analysis	None.	Ability to request test replicates for one sample, up to 20 replicates per sample per test.
Sample Analysis		
Wavelength (nm)	Halogen Lamp 340 to 800 nm 13 wavelengths: 340, 380, 410, 450, 480, 520, 540, 570, 600, 660, 700, 750 and 800 nm (maximum of 2 wavelengths)	Identical to predicate.
Type of Measurement	• End point assay • Rate assay • Fixed point assay • Electrode method (ISE)	Identical to predicate.
Throughput	Maximum 2000 photometric tests/hour/unit	Maximum 800 photometric tests/hour or 1200 tests/hour (photometric + ISE)

Feature	Predicate Device: AU5800 Clinical Chemistry Analyzer (K112412)	Proposed Device: DxC 700 AU Clinical Chemistry Analyzer
Reagent Handling		
Reagent Identification	Barcode and fixed position in the reagent carousel	Identical to predicate
Refrigerated Reagent On-board Capacity	System has 2 Reagent Refrigerators: Reagent 1: 54 bottle capacity Reagent 2: 54 bottle capacity	System has 2 Reagent Refrigerators: Reagent 1: 60 bottle capacity Reagent 2: 48 bottle capacity
ISE Reagents	3 ISEs	Identical to predicate.
Reagent Storage Temperature	Refrigeration temperature: 4 to 12 °C (39.2 to 53.6 °F)	Identical to predicate
Reagent Loading during Analysis	Not available. Prior to replacing reagent bottles, the AU5800 existing analysis must be completed and system must be in Pause Mode. This may take up to 24 minutes after customer requests reagent replacement.	Reagent bottles can be changed on the DxC 700 AU while the instrument continues to measure patient samples. On the DxC 700 AU, a reagent bottle can be added or changed within 5 minutes of request.
Computers/OS		
CPU	Single Intel Processor running Windows XP Pro 32bit	Intel Processor running Windows 7 64bit
Display/Monitor	19” display with touch screen	24” display with touch screen
Handheld Barcode Reader	Not Available	Provided for reading 1D and 2D barcodes
Software		
GUI Application	User interface unique to AU Chemistry systems	User interface which will be common to new Beckman Coulter IVD systems
Result Database Capacity	300 (Index) 9999 (Sample / Index) 400000 (test)	Identical to predicate.
User Help	PDF of IFU is available	HTML version of IFU is accessible with built-in interactive video.
Laboratory Information System (LIS) Interfaces	Similar with LIS ASTM 1394 and AU unique LIS protocol	Identical to predicate.
Laboratory Automation System (LAS) Interfaces	Beckman LAS interface for Rack Builder	Beckman LAS interface for Direct Track Sampling system

Feature	Predicate Device: AU5800 Clinical Chemistry Analyzer (K112412)	Proposed Device: DxC 700 AU Clinical Chemistry Analyzer
Real-Time Solutions (RTS) support	Interface to RTS via PRO*Service* protocol which is made by Beckman Coulter	Interface to RTS via PRO*Service* protocol which is made by Beckman Coulter Remote software installation capabilities.
External printers	Parallel port and USB interfaced printers	USB and LAN interfaced printers

8.0 Comparison testing

In order to further demonstrate the comparability of the predicate device, AU5800 and the candidate device, DxC 700 AU, the following reagent performance testing was performed on a representative number of assays:

Method Comparison
Matrix Comparison
Linearity
Sensitivity
Precision
Interference
In use (On board) & Calibrator Stability
Prozone
Sample Dilution

The DxC 700 AU chemistry analyzer uses the same Ion Selective Electrode (ISE) and reagents, as well as the same menu of reagents currently available on the AU5800. Representative assays from the AU chemistry menu were selected to demonstrate equivalency between the predicate device, AU5800, and the candidate device, DxC 700 AU.

The CRP Latex reagent can be used to measure CRP on the DxC 700 AU chemistry analyzer using two applications, a normal application and a high sensitivity (cardiac) application. Only the CRP high sensitivity (cardiac) application was reviewed in this submission as a representative assay.

9.0 Summary of Performance Data

This 510(k) submission provides the data necessary to demonstrate equivalence of the predicate device to the candidate device based on the performance validations and comparisons conducted between the representative reagents and analyzer platforms. Based on this data, the new DxC 700 AU Chemistry Analyzer is substantially equivalent to the referenced predicate.

9.1 Method Comparison with Predicate Device:

Method comparison and bias estimation experiments were designed using CLSI Guideline EP09-A3 *"Measurement Procedure Comparison and Bias Estimation Using Patient Samples; Approved Guideline"*. These patient correlation studies demonstrate equivalence between the predicate AU5800 and the candidate DxC 700 AU. A minimum of 100 serum, urine and CSF samples were tested over five days. No more than 20% of samples were either spiked or diluted to ensure a uniform distribution over the analytical range. Each spiked or diluted sample was made from an individual sample. All method comparisons met the required specifications as detailed in the tables below.

Table 9.1.1 Reagent Method Comparison Data

Analyte	# of samples	Units	Slope	Intercept	r
Sodium, Serum	120	mEq/L	1.007	-0.779	0.999
Sodium, Urine	130	mEq/L	1.014	-1.392	1.000
Potassium, Serum	122	mEq/L	0.988	0.048	0.999
Potassium, Urine	127	mEq/L	1.011	-0.149	1.000
Chloride, Serum	118	mEq/L	0.999	0.224	0.999
Chloride, Urine	129	mEq/L	1.036	-3.679	1.000
Glucose Serum	130	mg/dL	1.014	0.040	1.000
CRP Latex (HS) Serum	117	mg/L	1.013	-0.050	1.000

9.2 Matrix Comparison Study

Anticoagulation Studies were designed using CLSI EP09-A3: Measurement Procedure Comparison and Bias Estimation Using Patient Samples: Approved Guideline – Third Edition.

9.2.1 Glucose

The serum recovery from the Glucose test was compared to the corresponding EDTA, Sodium Fluoride Potassium Oxalate, Sodium Fluoride EDTA and Lithium Heparin for the same donor.

Table 9.2.1 Anticoagulant study results for Glucose reagent (OSR6x21)

Anticoagulant	No. of Samples tested	Sample Range (mg/dL)	Regression analysis	Specification	Result
EDTA	50	19.72 – 752.31	Slope: 0.999 Intercept: -0.099 R: 0.998 Bias: -0.199	Slope: 0.95-1.05 Intercept: ± 3.8mg/dL R: ≥ 0.95 Bias: ± 3% at 100 mg/dL	Pass
Sodium Fluoride Potassium Oxalate	50	19.72 – 752.31	Slope: 1.007 Intercept: 0.127 R: 0.998 Bias: 0.827		Pass
Lithium Heparin	50	19.72 – 752.31	Slope: 0.996 Intercept:-0.076 R: 0.998 Bias: -0.476		Pass
Sodium Fluoride EDTA	50	19.72 – 752.31	Slope: 1.005 Intercept: 0.133 R: 0.998 Bias: 0.633		Pass

9.2.2 CRP Latex

The serum recovery from the CRP Latex test (highly sensitive application) was compared to the corresponding EDTA and Lithium Heparin for the same donor.

Table 9.2.2 Anticoagulant study results for CRP Latex reagent (OSR6x99)

Anticoagulant	No. of Samples tested	Sample Range (mg/dL)	Regression analysis	Specification	Result
EDTA	52	0.34 – 73.11	Slope: 0.990 Intercept: -0.059 R: 0.9992 Bias: -2.97	Slope: 0.9-1.1 Intercept: ± 0.2 mg/L R: ≥ 0.95 Bias: ± 6% at 3mg/L	Pass
Lithium Heparin	52	0.34 – 73.11	Slope: 0.985 Intercept: -0.013 R: 0.9995 Bias: -1.93		Pass

9.3 Linearity/Assay Reportable Range:

Analytical range (linearity) studies were designed to meet the requirements of CLSI guidelines EP06-A "Evaluation of the Linearity of Quantitative Measurement Procedures: A Statistical Approach; Approved Guideline".

High and low pools were prepared and inter-diluted to achieve concentrations spanning the required linear range. Each dilution was assayed in quadruplicate on the DxC 700 AU. The performance data for the study demonstrates linearity throughout the claimed dynamic range of each assay, as represented in the tables below.

Table 9.3.1 Linearity Data

Analyte	Units	Slope	Intercept	r	Results	
					Linear From	Linear to
Sodium, Serum	mEq/L	1.0165	-1.6158	0.9999	6.69	245.97
Sodium, Urine	mEq/L	1.0506	-2.7363	0.9994	9.04	417.43
Potassium, Serum	mEq/L	1.0207	-0.1224	0.9996	0.14	12.44
Potassium, Urine	mEq/L	0.9883	0.0571	0.9999	1.02	223.47
Chloride, Serum	mEq/L	1.0362	-3.6836	0.9995	5.92	246.78
Chloride, Urine	mEq/L	1.0476	-3.5026	0.9994	14.10	421.31
Glucose Serum	mg/dL	0.9834	-0.0628	0.9999	5.20	843.18
CRP Latex (HS) Serum	mg/L	0.9894	0.0444	0.9995	0.15	92.49

9.4 Sensitivity (Detection Limits):

LoB, LoD and LoQ studies were designed primarily from CLSI guideline EP17-A2 "*Evaluation of Detection Capability for Clinical Laboratory Measurement Procedures Approved Guideline - Second Edition*. The experimental design consisted of replicate measurements on blank and low level samples using 2 lots of reagent across multiple days. A total of 60 blank replicates per reagent lot and 280 low level sample replicates per reagent lot were generated. This was comprised of 4 blank samples run 5-fold for 3 days, and 7 low level samples run 5-fold for 8 days.

The LoB, LoD, and LoQ results are summarised in the table below. All representative reagents met specifications and were below the claimed measuring range of the reagent.

Table 9.4.1 Sensitivity

Reagent	Units	Low End of Measuring Range	LoB	LoD	LoQ
Glucose, Serum	mg/dL	10	0	0.42	2.68
CRP Latex (HS), Serum	mg/L	0.2	0.04	0.08	0.08

9.5 Precision/Reproducibility:

Repeatability (within-run) and within-laboratory (total) precision studies were designed from CLSI guideline EP05-A3 *"Evaluation of Precision of Quantitative Measurement Procedures; Approved Guideline - Third Edition".* The precision was verified on the DxC 700 AU using 1 lot of reagent and 1 lot of calibrator and utilized duplicate sample analysis, twice daily, over the course of 20 days (n=80) for multiple sample levels. There was a minimum interval of two hours between the two runs each day.

All assays met the performance precision specifications and provide data to support the precision claims in the IFUs. The results are summarized in the below tables:

Table 9.5.1. Precision

Reagent	Sample Levels	Mean (n=80)	Repeatability (Within-run)		Within Laboratory (Total)	
			SD	% CV	SD	% CV
CRP Latex (HS) (mg/L)	Serum 1	0.49	0.019	3.84	0.017	3.48
	Serum 2	10.28	0.120	1.17	0.125	1.22
	Serum 3	50.08	0.314	0.63	0.389	0.78
	Serum 4	67.82	0.428	0.63	0.612	0.90
Glucose (mg/dL)	Serum 1	25.87	0.326	1.26	0.628	2.43
	Serum 2	60.55	0.501	0.83	0.815	1.35
	Serum 3	101.73	0.754	0.74	1.184	1.16
	Serum 4	280.55	2.386	0.85	2.530	0.90
	Serum 5	643.89	4.269	0.66	4.821	0.75
Sodium (mEq/L)	Serum 1	61.83	0.324	0.52	0.879	1.42
	Serum 2	109.70	0.318	0.29	0.638	0.58
	Serum 3	139.51	0.212	0.15	0.552	0.40
	Serum 4	167.78	0.309	0.18	0.834	0.50
Potassium (mEq/L)	Serum 1	2.48	0.009	0.36	0.016	0.64
	Serum 2	4.56	0.011	0.25	0.022	0.48
	Serum 3	6.46	0.021	0.33	0.039	0.60
	Serum 4	8.35	0.035	0.42	0.080	0.96
Chloride (mEq/L)	Serum 1	76.47	0.149	0.19	0.510	0.67
	Serum 2	105.25	0.270	0.26	0.443	0.42
	Serum 3	151.82	0.401	0.26	1.025	0.68
Sodium (mEq/L)	Urine 1	21.98	0.261	1.19	0.414	1.89
	Urine 2	98.73	0.420	0.43	1.308	1.32
	Urine 3	245.49	0.951	0.39	3.191	1.30
	Urine 4	353.40	0.933	0.26	4.092	1.16
Potassium (mEq/L)	Urine 1	10.50	0.047	0.45	0.127	1.21
	Urine 2	33.62	0.128	0.38	0.611	1.82
	Urine 3	101.11	0.596	0.59	1.308	1.29
	Urine 4	171.44	1.145	0.67	2.435	1.42
Chloride (mEq/L)	Urine 1	25.50	0.173	0.68	0.559	2.19
	Urine 2	84.46	0.249	0.29	0.508	0.60
	Urine 3	148.47	0.383	0.26	0.758	0.51
	Urine 4	290.56	1.737	0.60	3.640	1.25
	Urine 5	364.05	1.716	0.47	4.157	1.14

9.6 In-Use and Calibration Stability Verification (EP25-A):

This protocol followed CLSI EP25-A guideline "*Evaluation of Stability of In Vitro Diagnostic Reagents; Approved Guideline"*; The aim was to verify the 30 and 90 day on-board claim for the representative reagents and to verify the 1 day calibration stability claim for the ISEs on the DxC 700 analyzer.

Testing was performed using one reagent lot (where appropriate) and one calibrator lot on the DxC 700 analyzer. Calibration (as required) was performed on the initial day of testing and controls were run in duplicate. At each time-point the reagents were calibrated (if required) and controls were run in duplicate. Controls were run in duplicate on Day 1 + greater than 2hrs for the ISEs. The mean of the control replicates was calculated and the bias of this result to the mean of the control on Day 0 was calculated. The final time-points exceeded the claims on the reagent and ISE IFUs. For the reagents, linearity was assessed at the final time point.

A summary of in-use and calibration stability specifications and results are detailed in the tables below. All results were within specification and provide data to support the on-board and calibrations stability claims in the reagent and ISE IFUs.

Table 9.6.1 Reagent In-Use and Calibration Stability Specifications

Reagent	Application	Onboard Stability Claim (Days)	Calibration Stability Claim (Days)
CRP Latex (HS)	Serum	90	90
Glucose	Serum	30	30

Table 9.6.2 ISE Calibration Stability Specifications

Product Name	Sample Type	Calibration Stability Claim (Days)
Sodium	Serum	1
	Urine	1
Potassium	Serum	1
	Urine	1
Chloride	Serum	1
	Urine	1

9.7 Interferences (Analytical specificity):

Interference studies were designed based on CLSI Guideline EP07-A2: "Interference Testing in Clinical Chemistry; Approved Guideline - Second Edition".

All test samples were assayed in quadruplicate at two analyte levels. The sample pools tested were at different levels of interferents to determine the magnitude of their effect (if any). The data analysis involved calculating the difference in recovery of the samples with and without the potential interfering substances. The results are summarized below. All interferences met the required specifications on the DxC 700 AU analyzer.

Table 9.7.1 Chloride LIH Tolerance

SUBSTANCE	SOURCE	LEVEL TESTED*	OBSERVED EFFECT
Bilirubin (unconjugated)	Porcine	40 mg/dL	NSI[a]
Hemoglobin	RBC hemolysate	500 mg/dL	NSI
Lipemia	Intralipid[b]	500 mg/dL	NSI

Table 9.7.2 Potassium LIH Tolerance

SUBSTANCE	SOURCE	LEVEL TESTED*	OBSERVED EFFECT
Bilirubin (unconjugated)	Porcine	40 mg/dL	NSI[a]
Hemoglobin	RBC hemolysate	70 mg/dL	NSI
Lipemia	Intralipid[b]	500 mg/dL	NSI

Table 9.7.3 Sodium LIH Tolerance

SUBSTANCE	SOURCE	LEVEL TESTED*	OBSERVED EFFECT
Bilirubin (unconjugated)	Porcine	40 mg/dL	NSI[a]
Hemoglobin	RBC hemolysate	250 mg/dL	NSI
Lipemia	Intralipid[b]	500 mg/dL	NSI

*Level Tested represents the maximum concentration of interferent tested where no significant interference was observed.
a = NSI = No Significant Interference (Chloride ±2.5%, Potassium ±0.25 mEq/L, Sodium ±2mEq/L)
b = Intralipid is a registered trademark of KabiVitrum, Inc., Clayton, NC 27250

Table 9.7.4 Glucose and CRP (HS) Interference Data

Reagent	Interference Threshold		
	*Lipemic (Intralipid) ±	Icteric (Unconjugated) ±	Hemolytic ±
Glucose, Serum	10% at 700 mg/dL	10% at 40 mg/dL	10% at 500 mg/dL
CRP Latex (HS), Serum	Intralipid (1000 mg/dL) intf. < 10% at CRP conc. of 1 mg/L	Bilirubin (40 mg/dL) intf. < 5% at CRP conc. of 1 mg/L	hemolysate (500 mg/dL) intf. < 5% at CRP conc. Of 1 mg/L

* Claim based on Intralipid: a 20% IV fat emulsion used to emulate extremely turbid samples.

9.8 Prozone

Testing was carried out to verify the prozone performance on the DxC 700 AU using CRP Latex (High Sensitivity application) as the representative assay. Human serum was spiked with human CRP to create a prozone high pool of > 750 mg/L. The CRP concentration was verified using three replicates of three dilutions within the measuring range. Eleven dilutions of the high prozone pool were then prepared and ran n=3 to confirm prozone performance. Testing demonstrates that samples with CRP concentrations up to 750 mg/L will not generate falsely low results within the analytical range.

10.0 Conclusion

The submission provides the data necessary to demonstrate this equivalence based on the performance validations and comparisons conducted between the representative reagents and analyzer platforms. Based on this data, the new DxC 700 AU Chemistry Analyzer is substantially equivalent to the referenced predicate(s).

This 510(k) summary is being submitted in accordance with the requirements of the Safe Medical Device Act of 1990 and the implementing regulation 21 CFR 807.92.