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BECKMAN COULTER

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Abbreviated 510(k) Summary for the
Beckman Coulter UniCel® DxH 800 COULTER® Cellular Analysis System

1.0 **Submitted By:**

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2.0 **Date Submitted:**

March 13th, 2012

3.0 **Device Name and Classification**

Proprietary Name:
UniCel® DxH 800 COULTER® Cellular Analysis System

Classification Number: 21 CFR § 864.5220 – Automated differential cell counter

Classification: Class II

Product Code: GKZ

Panel: Hematology

4.0 **Predicate Device:**

Predicate Product	510(K) Number	Date Cleared	Classification	21 CFR	Product Code
UniCel® DxH 800 COULTER® Cellular Analysis System	K081930	12/19/2008	Class II	864.5220	GKZ

The updated DxH 800 system uses the same reagents, controls and calibrators as the cleared device; there are no changes to these products as a result of the changes prompting this submission of the DxH 800.

5.0 **Description:**

The updated DxH 800 with software version 2.0, the subject of this submission, uses the same principles of operation, reagents, controls and calibrators as the original cleared device.

The UniCel® DxH 800 COULTER® Cellular Analysis System (DxH 800) is intended for In Vitro Diagnostic Use in clinical laboratories. The DxH 800 System provides automated complete blood count, leukocyte differential, nucleated red blood cell (NRBC) enumeration and reticulocyte analysis as well as an automated method for enumeration of the Total Nucleated Cells (TNC) and Red Blood Cells (RBC) in body fluids.

The DxH 800 System is intended to separate patients with normal hematological parameters from patients who need additional studies of any of these parameters. These studies might include further measurements of cell size and platelet distribution, manual WBC differential or any other definitive test that helps diagnose the patient's condition.

The DxH 800 system is comprised of the analyzer (see Figure 1 and Table 1), an optional floor stand (see Figure 2 and Table 2), and a suite of analytical reagents, quality control and calibration reagents, and reagents for system cleaning (see Table 3).

Figure 1: Bench top DxH 800 System

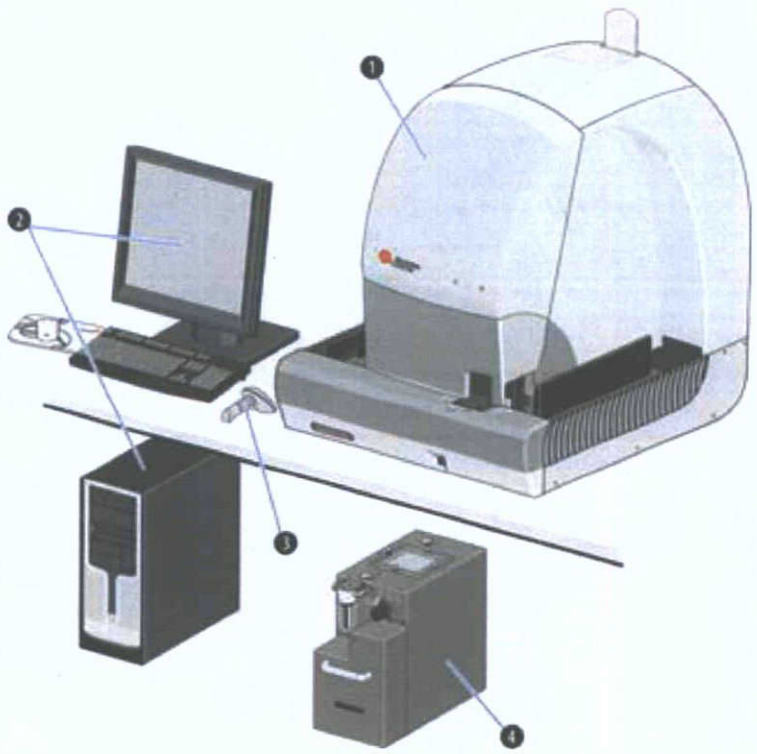


Figure 1 #	System Components	Description / Function
Item 1	Specimen Processing Module (SPM)	Process specimens – provides functionality for specimen transport, specimen identification and specimen mixing. Mixed specimens are sampled and required volumes of specimen are mixed and incubated with applicable reagents. The prepared specimen/reagent mix is presented to applicable analytical modules where the analysis and raw data generation occurs. Raw data is sent to System Manager for analysis.
Item 2	System Manager	Personal Computer (PC) based workstation running system application specific software – Provides system control functions for the SPM. Receives raw data from SPM and performs analysis to generate applicable parameter results. Provides data management and storage, provides test order management, results review and reporting, quality control functionality, diagnostics and maintenance procedures. User interaction is provided via touch screen, keyboard and mouse. Connects with laboratory information systems (LIS).
Item 3	Hand held Barcode scanner	Provides user the capability for manual sample identification and entry of barcoded reagent information for reagent tracking
Item 4	Pneumatic Supply Module (PSM)	Supplies vacuum and pressure to the SPM for system operation

Table 1: Description of DxH 800 components

Figure 2: DxH 800 System and Floor stand

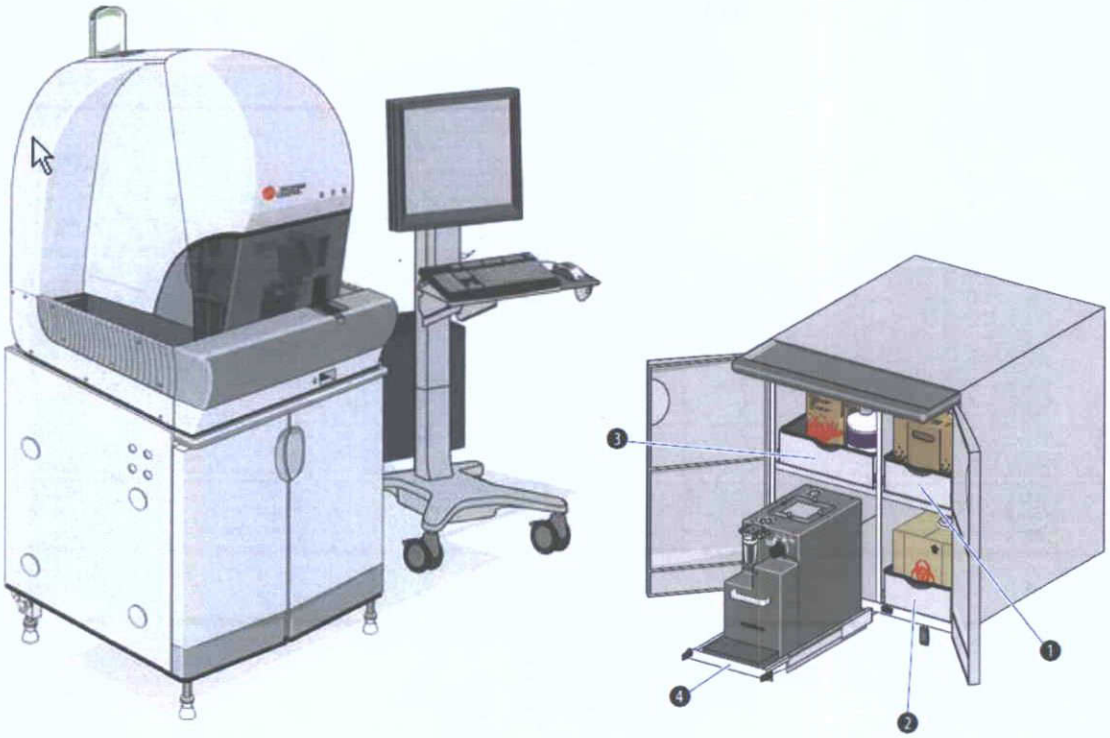


Figure 2 #	System Components	Description / Function
	Floor Stand (Optional)	Provides self-contained support for the SPM as well as easy access storage for reagents and waste containers. Additionally, the Floor Stand houses the Pneumatic Supply module on an integrated pull-out shelf.
Item 1	Reagent Drawer	Provides storage and SPM supply tubing for connection of two 10L Diluent containers
Item 2	Waste Drawer	Provides storage and SPM supply tubing for connection of two 10L waste containers
Item 3	Reagent Drawer	Provides storage and SPM supply tubing for connection of Cell Lyse, Diff Pack, Retic Pack and Cleaner reagents
Item 4	Pneumatic Supply Module	Provides storage and pressure vacuum supply connections for SPM

Table 2: DxH 800 Floor stand

Analytical Reagents:	Description / Function
COULTER® DxH Diluent	A cyanide-free, isotonic buffered saline solution, used to dilute the specimen prior to analysis. Used for rinsing the Sample Processing Module (SPM) components between sample analyses.
COULTER® DxH Cell Lyse	A cyanide-free lytic reagent that lyses red blood cells to allow enumeration and sizing of white blood cell cells. Works in conjunction with COULTER DxH Diluent to generate a stable hemoglobin measurement. Used to discriminate nucleated red blood cells from white blood cells
The COULTER® DxH Diff Pack	The Pack contains two reagents; a cell lytic reagent and a cell preservative reagent. The lytic reagent is a cyanide-free reagent that dilutes the blood sample, and lyses red blood cells to allow WBC differentiation. The preservative reagent neutralizes the lytic reagent and preserves the white blood cells for measurement in the flow cell. Together, they provide the five-part differential utilizing the VCSn technology.
COULTER® DxH Retic Pack	The pack contains a reticulocyte stain reagent and a reticulocyte-clearing reagent. The reticulocyte stain reagent is a cyanide-free reagent that uses a dye to stain reticulocytes. The reticulocyte-clearing reagent is a cyanide-free reagent that stabilizes the dye-reticulum complex to enhance discrimination of reticulocytes from mature red blood cells utilizing the VCSn technology.
COULTER® DxH Cleaner	A cyanide-free, aldehyde-free cleaning agent that degrades residual materials so that they may be flushed from the system with the diluent.
Controls	**Description / Function**
COULTER® 6C Cell Control	An integrated control that enables monitoring of system performance for all directly measured and calculated CBC, Diff and NRBC parameters.
COULTER® Retic-X Cell Control	A control product for monitoring system performance of the reticulocyte parameters.
COULTER® LIN-X Linearity Control	A control product for the verification of the reportable range, and calibration assessment of the WBC, RBC, HGB, and PLT parameters.
COULTER® Body Fluid Control	A control product for monitoring system performance of the body fluid cycle's RBC and TNC count parameters. Additionally, COULTER Body Fluid Control can be used for verification of the measuring range of the TNC and RBC parameters in the body fluid panel.
COULTER® LATRON™ CP-X Control	A control product used to monitor the volume, conductivity and light scatter parameter measurements.
Calibrators	**Description / Function**
COULTER® S-CAL® Calibrator	Calibrator for determining calibration factors to ensure accurate measurements of directly measured CBC parameters. Assigned assay values are traceable to reference methods.

Table 3: DxH 800 Analytical reagent, controls and calibrator

Parameters

The system has the capability to determine the hematologic parameters shown in Table 4.

WBC	White Blood Cell count
RBC	Red Blood Cell count (for Whole Blood and Body Fluids)
HGB	Hemoglobin
HCT	Hematocrit
MCV	Mean Corpuscular Volume
MCH	Mean Corpuscular Hemoglobin
MCHC	Mean Corpuscular Hemoglobin Concentration
RDW	Red Cell Distribution Width
RDW-SD	Red Cell Distribution Width Standard Deviation (SD)
PLT	Platelet count
MPV	Mean Platelet Volume
NE	Neutrophil percent
LY	Lymphocyte percent
MO	Monocyte percent
EO	Eosinophil percent
BA	Basophil percent
NE#	Neutrophil absolute number
LY#	Lymphocyte absolute number
MO#	Monocyte absolute number
EO#	Eosinophil absolute number
BA#	Basophil absolute number
NRBC	Nucleated Red Blood Cell percent
NRBC#	Nucleated Red Blood Cell absolute number
RET	Reticulocyte percent
RET#	Reticulocyte absolute number
MRV	Mean Reticulocyte Volume
IRF	Immature Reticulocyte Fraction
TNC	Total Nucleated Cell (Body Fluids)

Table 4: DxH 800 parameters

Recommended anticoagulants

Whole blood and pre-diluted anti-coagulated blood	K_2 or K_3 - EDTA
Serous fluids	K_2 or K_3 - EDTA
Synovial fluids (pretreated with Hyaluronidase)	K_2 or K_3 - EDTA or heparin

Specimen Processing Methods

The DxH 800 provides the user with the ability to obtain a variety of combinations of parameter results through the use of analytical test panels. In addition the specimen analysis can occur via a number of sampling methods on the analyzer.

The test panels and the parameters reported, along with the sampling method that are available to the user are shown in Table 5.

Test Panel	Reported Parameters	Specimen type	Sampling Method
Complete Blood Count (CBC)	▪ WBC, RBC, HGB, HCT, MCV, MCH, MCHC, RDW, RDW-SD, PLT, MPV	Whole Blood	▪ Automated Cassette Closed Vial ▪ Manual Single Tube Closed Vial ▪ Manual Single Tube Open Vial
CBC and Differential inc NRBC (CD)	▪ WBC, RBC, HGB, HCT, MCV, MCH, MCHC, RDW, RDW-SD, PLT, MPV, ▪ NE%, NE#, LY%, LY#, MO%, MO#, EO%, EO#, BA%, BA#, NRBC% and NRBC#.	Whole Blood	▪ Automated Cassette Closed Vial ▪ Manual Single Tube Closed Vial ▪ Manual Single Tube Open Vial
CBC, Differential inc NRBC and Retic (CDR)	▪ WBC, RBC, HGB, HCT, MCV, MCH, MCHC, RDW, RDW-SD, PLT, MPV, ▪ NE%, NE#, LY%, LY#, MO%, MO#, EO%, EO#, BA%, BA#, NRBC%, NRBC#, ▪ RET%, RET#, MRV, IRF	Whole Blood	▪ Automated Cassette Closed Vial ▪ Manual Single Tube Closed Vial ▪ Manual Single Tube Open Vial
CBC and Retic (CR)	▪ WBC, RBC, HGB, HCT, MCV, MCH, MCHC, RDW, RDW-SD, PLT, MPV, ▪ RET%, RET#, MRV, IRF	Whole Blood	▪ Automated Cassette Closed Vial ▪ Manual Single Tube Closed Vial ▪ Manual Single Tube Open Vial
Retic (R)	▪ RET% RET#, MRV, IRF	Whole Blood	▪ Automated Cassette Closed Vial ▪ Manual Single Tube Closed Vial ▪ Manual Single Tube Open Vial
Pre-dilute (PreDilx5)	▪ WBC, RBC, HGB, HCT, MCV, MCH, MCHC, RDW, RDW-SD, PLT, MPV	1 in 5 Pre-diluted whole blood	▪ Manual Single Tube Open Vial
Body Fluid (BF)	▪ TNC, RBC	Body Fluid (cerebrospinal, serous and synovial)	▪ Manual Single Tube Open Vial

Table 5: DxH 800 test panels, reported parameters and sampling methods

Test Principle

The Coulter Principle of automated cell counting and sizing is used in the analysis of the whole blood and body fluid specimens.

Each cell suspended in a conductive liquid (diluent) acts as an insulator. As each cell goes through the aperture, it momentarily increases the resistance of the electrical path between two submerged electrodes on either side of the aperture. This causes a measurable electronic pulse. While the number of pulses indicates particle count, the amplitude of the electrical pulse is proportional to the cell volume. These pulses are sent to the Signal Conditioner for analog to digital conversion. Pulse counts and digitized pulse measurements are sent to the System Manager for processing by the algorithms where the reported parameter values, flags and histograms are generated.

The lytic reagent used for the white cell count prepares the blood so the system can count leukocytes and measure the amount of hemoglobin. The lytic reagent rapidly and simultaneously destroys the erythrocytes and converts a substantial proportion of the hemoglobin to a stable pigment while it leaves leukocyte nuclei intact. The absorbance of the pigment is directly proportional to the hemoglobin concentration of the sample.

Hemoglobin is measured photometrically at 525 nm using the sample from the white cell analysis. Clean diluent is introduced into the cuvette during each operating cycle and is used as a blank in the calculation of the HGB.

The COULTER® VCSn technology is used to determine the white cell differential, nucleated red blood cell count and reticulocyte parameters along with associated flags, messages, histograms and dataplots.

The sample preparation and analysis uses specific reagents and analytical processes for the WBC differential, NRBC and Retic analysis. The prepared sample is delivered to the flow cell for sample detection. As the cells pass through the sensing zone, a diode laser illuminates the particles causing light scatter and light absorption. Simultaneously to the light scatter measurements, cell volume and cell conductivity are also measured.

The data collected during each of the analytical processes is transferred to the System Manager where the digital raw values are processed by the algorithm using mathematical approaches designed for finding optimal separation between clusters of data. The identified clusters are used to calculate the frequency of cells within each population, generate parameter values, flags, histograms and data plots.

6.0 Intended Use:

The UniCel® DxH 800 COULTER® Analyzer is a quantitative multi-parameter, automated hematology analyzer for *in vitro* diagnostic use in screening patient populations found in clinical laboratories.

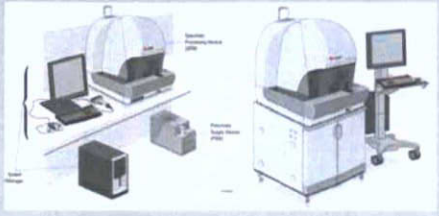
The UniCel® DxH 800 COULTER® Analyzer identifies and enumerates the parameters indicated below on the following sample types:

- Whole Blood (Venous and Capillary)
  - WBC, RBC, HGB, HCT, MCV, MCH, MCHC, RDW, RDW-SD, PLT, MPV, NE%, NE#, LY%, LY#, MO%, MO#, EO%, EO#, BA%, BA#, NRBC%, NRBC#, RET%, RET#, MRV, IRF
- Pre-Diluted Whole Blood (Venous and Capillary)
  - WBC, RBC, HGB, HCT, MCV, MCH, MCHC, RDW, RDW-SD, PLT, MPV
- Body Fluids (cerebrospinal, serous and synovial)
  - TNC and RBC

Indication for Use.

See Intended Use above.

7.0 **Comparison to Predicate:** The tables below compare the predicate DxH 800 and the updated DxH 800.

Characteristic	**UniCel® DxH800 Predicate** 	**UniCel® DxH800 Update Test Device (Software 2.0)** 

Intended Use and Function	The UniCel® DxH 800 Analyzer is a quantitative, automated hematology analyzer for *in vitro* diagnostic use in screening patient populations found in clinical laboratories.
	
	The UniCel® DxH 800 Analyzer provides a:
	
	▪ Complete Blood Count (CBC), Leukocyte 5 Part Differential (Diff), Reticulocyte (Retic) and Nucleated Red Blood Cell (NRBC) on whole blood
	▪ Total Nucleated Count (TNC) and Red Cell Count (RBC) on Body Fluids (cerebrospinal, serous and synovial) (BF)
		The Indications for Use for the updated DxH 800 have not changed. The statement has been reworded to provide clarity and specific information on the parameters reported from each of the specimen types that are analyzed on the device.
		
		The UniCel® DxH 800 Analyzer is a quantitative multi-parameter, automated hematology analyzer for in vitro diagnostic use in screening patient populations found in clinical laboratories.
		The UniCel® DxH 800 Analyzer identifies and enumerates the parameters indicated below on the following sample types:
		• Whole Blood (Venous and Capillary)
		  • WBC, RBC, HGB, HCT, MCV, MCH, MCHC, RDW, RDW-SD, PLT, MPV, NE%, NE#, LY%, LY#, MO%, MO#, EO%, EO#, BA%, BA#, NRBC%, NRBC#, RET%, RET#, MRV, IRF
		• Pre-Diluted Whole Blood (Venous and Capillary)
		  • WBC, RBC, HGB, HCT, MCV, MCH, MCHC, RDW, RDW-SD, PLT, MPV
		• Body Fluids (cerebrospinal, serous and synovial)
		  • TNC and RBC

Principles of Measurement		
WBC, RBC, MCV, Plt, BF-TNC, BF-RBC	Aperture impedance (Coulter® Principle)	Same as predicate DxH 800
Hgb	Spectrophotometric	Same as predicate DxH 800
WBC Differential,	VCSn Technology using : ▪ Aperture impedance (DC) ▪ Conductivity (RF) ▪ Laser Light Scatter (Multiple angles) ▪ Laser Light Absorbance	Same as predicate DxH 800
Retic	VCSn Technology using : ▪ Aperture impedance (DC) ▪ Conductivity (RF) ▪ Laser Light Scatter (Multiple angles) ▪ Laser Light Absorbance	Same as predicate DxH 800
NRBC	VCSn Technology using : ▪ Aperture impedance (DC) ▪ Conductivity (RF) ▪ Laser Light Scatter (Multiple angles) ▪ Laser Light Absorbance	Same as predicate DxH 800
Reagents		
Analysis Reagents	COULTER® DxH Diluent COULTER® DxH Diff Pack COULTER® DxH Retic Pack COULTER® DxH Cell Lyse	Same as predicate DxH 800
Quality Controls & Calibrator	COULTER® 6C Cell Control COULTER® Latron™ CP-X Control COULTER® RETIC-X Cell Control COULTER® LIN-X Control COULTER® Body Fluids Control COULTER® S-CAL® Calibrator kit	Same as predicate DxH 800
Cleaning Agent	COULTER® DxH Cleaner	Same as predicate DxH 800

Pre-Analytic Features		
System configuration	Bench top or Optional Floor Stand - provides self-contained support for the analyzer as well as easy access storage for reagents and waste containers. PC based workstation running Microsoft Windows XP application specific software Handheld Barcode Scanner Printer	Same as predicate DxH 800
Sampling Mechanism	Single tube presentation – open and closed vial sampling Automated presentation – closed vial sampling from 5 position cassette. Maximum initial load capacity 20 racks.	Same as predicate DxH 800 with: • Updates to provide dedicated cassette and mixing profile for specific tubes.
Mechanisms for processing	Mechanisms to achieve process of : automated cassette transportation and specimen mixing (by rocking), sample aspiration, sample preparation, sample and reagent presentation to analytical modules, sample analysis, raw data collection, algorithmic processing and data reporting Cassette transportation by magnetic drive allowing multi-directional moves and capability to return cassette to sampling position for repeat / reflex testing.	Same as predicate DxH 800 with: • Updates for device reliability, manufacturability and serviceability.
Sample identification	Sample aspiration module (SAM) mounted barcode reader for automated barcode reading of cassette and sample tube identifiers Manual barcode scanning of sample tube identifier (Handheld scanner) Manual keyboard entry of sample identifier	Same as predicate DxH 800 with: • Corrections to address sample identification related recalls. • Updates to add capability for host query communication with Laboratory Information System (LIS).

Sample Processing		
Aspiration Pathway	Single sampling probe and common aspiration pathway used for all sample presentation modes.	Same as predicate DxH 800
Sample aspiration volume	Automatic, cap-piercing : 165 µL Single tube - open-vial and cap pierce: 165 µL Predilute 165 µL - fixed ratio of 1 in 5 dilution of blood with diluent	Same as predicate DxH 800
Sample Preparation	Rotary blood sampling valve (BSV) and syringe aspiration / dispense for blood segmentation / distribution Rotary ceramic piston pumps driven by stepper motors for reagent delivery CBC dilutions mixed vial tangential delivery to baths VCSn dilutions mixed by air jet in reaction chambers Reagents are temperature stabilized for analysis reactions	Same as predicate DxH 800
Throughput : Automated cassette processing	CBC ≥100 specimens per hour CBC/Diff ≥100 specimens per hour CBC/Diff/NRBC ≥ 90 specimens per hour Any cycle with Retic ≥45 specimens per hour Throughput is based on normal specimens – analytical cycle times are increased with cytopenic specimens.	Same as predicate DxH 800
Data Analysis	Raw information is digitized from all analytical modules and passed to workstation for algorithmic processing. Algorithms using advanced mathematical methods for population differentiation and flagging centralized within workstation	Same as Predicate DxH 800 with: • Enhancements for improved flagging
Data reporting	Workstation display graphics, hardcopy printing and transmission to Laboratory Information System (LIS)	Same as Predicate DxH 800 with: • Corrections to address data reporting related recalls. • Updates to include revised LIS communication protocol to improve software performance and additional printer support functions.

System Control		
Controlling software	System software (embedded and workstation) designed specific to support all features of DxH 800 The software system consists of a Data Manager component, a System Manager component (including algorithms), the User Interface, all of which are resident in the Workstation. In addition an Embedded Application is resident in the analyzer. The Embedded application uploads from the workstation on system power-up. Extensive real time monitoring and reporting of system status including: Component and module activities, System Voltages and Currents System Pressure and Vacuum System Temperatures Motor activity Mechanism Sensor status Reagent Pump Operation Raw data collection	Same as DxH 800 predicate with: • Corrections to address software related recalls. • Updates to improve removal of cleaning agent during Shutdown and Daily Checks and monitoring of Sample and Sheath pressure sensors reading to detect when sensors are disconnected • Software architecture changes that provide a foundation for future product enhancements and platform expansion.
Performance		
Performance Claims	As stated in the Instructions for Use for the predicate device.	Performance claims are the same as the predicate DxH 800 with the following updates based on alignment to current clinical testing standards • Updated Operating and Measuring ranges for selected parameters o To align selected parameter lower limits with background, Limit of Blank, Limit of Detection and Limit of Quantitation. o To align selected upper parameter limits with values seen in clinical conditions. • Updated NRBC Carryover specification

8.0 Summary of Performance Data:

Study	Testing Approach	FDA Guidance Documents	Standards / References	510(k) Testing Summary
Accuracy - Comparability Whole blood and Body fluid	Whole blood and Body Fluid accuracy (comparability) testing was performed to demonstrate the updated DxH 800 meets accuracy claims (Bias and/or Difference) limits over the measuring ranges defined in product labeling.	Class II Special Controls Guidance Section 8 - Accuracy	Standards Documents • Validation, Verification, and Quality Assurance of Automated Hematology Analyzers, Approved Standard – 2nd Edition; June 2010; CLSI H26-A2 (FDA Standards Recognition # 7-210) • Method Comparison and Bias Estimation Using Patient Samples; CLSI EP9-A2 (FDA Standards Recognition # 7-92) • Reference Leukocyte (WBC) Differential Count (Proportional) and Evaluation of Instrumental Methods; CLSI H20-A2 (FDA Standards Recognition # 7-165) • Body Fluid Analysis for Cellular Composition; CLSI H56-A (FDA Standards Recognition # 7-163)	Analysis of the data collected demonstrates that the updated DxH 800 meets the performance requirements and provides results within acceptance limits for parameters reported from whole blood, when compared to the predicate device and for differential parameters when compared to manual reference results. In addition the updated DxH 800 meets the performance requirements and provides results within acceptance limits for parameters reported from body fluid, when compared to the manual chamber count.
Accuracy - Comparability Analytical cycles	Testing was performed on the updated DxH 800 to demonstrate equivalency of results (within defined limits) between the whole blood analytical cycles (test panels), CBC (C), CBC/DIFF (CD), CBC/DIFF/Retic (CDR), CBC/Retic (CR), Retic (R) when specimens are analyzed using the automated closed vial sample processing method. In addition testing was performed to demonstrate equivalency between specimens analyzed as whole blood and as Pre-dilute (PD) specimens.	Class II Special Controls Guidance Section 8 - Accuracy	Standards Documents • Validation, Verification, and Quality Assurance of Automated Hematology Analyzers, Approved Standard - 2nd Edition; June 2010; CLSI H26-A2 (FDA Standards Recognition # 7-210) • User Verification of Performance for Precision and Trueness Approved Guideline; Approved Guideline - Second Edition; June 2005; CLSI EP15-A2 (FDA Standards Recognition # 7-153)	Analysis of the data collected demonstrates that the updated DxH 800 meets the performance requirements and provides comparable results for all parameters reported from specimens analyzed as whole blood in the available analytical cycles and when analyzed as whole blood and pre-dilute samples.

Study	Testing Approach	FDA Guidance Documents	Standards / References	510(k) Testing Summary
Accuracy – Comparability Sampling modes	Testing was performed to demonstrate comparability between the sampling modes available on the updated DxH 800. Testing compared the automated closed vial with the manual closed vial sampling and the manual closed vial with the manual open vial methods using the CBC, Differential and Retic analytical cycle.	Class II Special Controls Guidance Section 8 - Accuracy	Standards Documents • Validation, Verification, and Quality Assurance of Automated Hematology Analyzers, Approved Standard - 2nd Edition; June 2010; CLSI H26-A2 (FDA Standards Recognition # 7-210) • User Verification of Performance for Precision and Trueness Approved Guideline; Approved Guideline - Second Edition; June 2005; CLSI EP15-A2 (FDA Standards Recognition # 7-153)	Analysis of the data collected demonstrates that the updated DxH 800 meets performance requirements to provide comparable results for all parameters reported, for specimens analyzed using the sampling methods available (automated closed vial, manual closed vial and manual single tube open vial).
Reproducibility	Testing was performed on the updated DxH 800 to demonstrate the long term imprecision of the device. Testing was performed using multiple levels of control materials for CBC, Differential, NRBC, Retic and Body Fluid parameters.	Class II Special Controls Guidance Section 9 - Precision	Standards Documents • Validation, Verification, and Quality Assurance of Automated Hematology Analyzers, Approved Standard - 2nd Edition; June 2010; CLSI H26-A2 (FDA Standards Recognition # 7-210) • Evaluation of Precision Performance of Quantitative Measurement Methods; Approved Guideline – Second edition; August 2004. CLSI EP05-A2 (FDA Standards Recognition # 7-110)	Analysis of the data collected demonstrates that the updated DxH 800 meets the performance requirements (within acceptance limits) for reproducibility (long term imprecision) using control products.

Study	Testing Approach	FDA Guidance Documents	Standards / References	510(k) Testing Summary
Repeatability	Testing was performed on the updated DxH 800 to demonstrate the short term imprecision of the device. Testing was performed using replicate measurements of specimens in the normal range, at medical decision levels and over the analytical measuring interval. Testing was performed on whole blood, pre-diluted whole blood and body fluid specimens	Class II Special Controls Guidance Section 9 - Precision	Standards Documents • Validation, Verification, and Quality Assurance of Automated Hematology Analyzers, Approved Standard - 2nd Edition; June 2010; CLSI H26-A2 (FDA Standards Recognition # 7-210) • Evaluation of Precision Performance of Quantitative Measurement Methods; Approved Guideline – Second edition; August 2004. CLSI EP05-A2 (FDA Standards Recognition # 7-110) • Body Fluid Analysis for Cellular Composition; Approved Guideline, June 2006. CLSI H56-A (FDA Standards Recognition # 7-163) Reference Documents • Hubl, W.; Tlustos, L.and M. Bayer, Use of precision profiles to evaluate precision of the automated leukocyte differential. Clinical Chemistry 42:7, 1068, 1996.	Analysis of the data collected demonstrates that the updated DxH 800 meets performance requirements for repeatability, (within acceptance limits) for all parameters reported.

Study	Testing Approach	FDA Guidance Documents	Standards / References	510(k) Testing Summary
Performance LoB. LLoD, LLoQ	Limit of Blank, Lower Limit of Detection and Lower Limit of Quantitation testing was performed for the parameters where there is a clinical interest (medical decision level) on very low or near zero values. Whole blood • WBC and PLT Body Fluid • TNC and RBC	Class II Special Controls Guidance Section 10 - Performance	Standards Documents • Validation, Verification, and Quality Assurance of Automated Hematology Analyzers, Approved Standard - 2nd Edition; June 2010; CLSI H26-A2 (FDA Standards Recognition # 7-210) • Protocols for Determination of Limits of Detection and Limits of Quantitation; CLSI EP17-A (FDA Standards Recognition # 7-194)	Analysis of the data collected demonstrates that the updated DxH 800 meets the performance requirements for LoB, LLoD and LLoQ results (within acceptance limits), for the WBC and PLT parameters in whole blood and the BF-TNC and BF-RBC parameters in body fluids.
Performance Clinical Sensitivity and Specificity	Clinical Sensitivity and Specificity are used to assess the ability of a test to detect presence or absence of a condition/abnormality. For the updated DxH 800, Clinical Sensitivity and Specificity was used to assess the WBC Differential Suspect message flagging capability of the system.	Class II Special Controls Guidance Section 10 - Performance	Standards Documents • Validation, Verification, and Quality Assurance of Automated Hematology Analyzers, Approved Standard – 2nd Edition; June 2010; CLSI H26-A2 (FDA Standards Recognition # 7-210) • Reference Leukocyte (WBC) Differential Count (Proportional) and Evaluation of Instrumental Methods; CLSI H20-A2 (FDA Standards Recognition # 7-165) Reference Documents • The International Consensus Group for Hematology Review: Suggested Criteria for Action Following Automated CBC and WBC Differential Analysis; Laboratory Hematology, 11:83-90, 2005	Analysis of the data collected demonstrates that the updated DxH 800 provided equivalent or improved performance for Clinical Sensitivity and Specificity as compared to the predicate device analyzing the same data set.

Study	Testing Approach	FDA Guidance Documents	Standards / References	510(k) Testing Summary
Linearity Whole blood and Body fluid	Testing was performed on the updated DxH 800 to demonstrate the linearity of the device. Linearity was assessed by demonstrating that the reported results are directly proportional to the concentration of the measurand in a test sample for whole blood and body fluids.	Class II Special Controls Guidance Section 11 - Linearity	Standards Documents • Validation, Verification, and Quality Assurance of Automated Hematology Analyzers, Approved Standard - 2nd Edition; June 2010; CLSI H26-A2 (FDA Standards Recognition # 7-210) • Evaluation of the Linearity of Quantitative Measurement; Approved Guideline; April 2003. CLSI EP06-A (FDA Standards Recognition # 7-193)	Analysis of the data collected demonstrates that the updated DxH 800 meets the performance requirements and provides linear results, within acceptance limits, for Whole blood and Body Fluid.
Carryover Whole blood and Body fluid	Testing was performed to demonstrate whole blood and body fluid carryover performance of the updated DxH 800 by determining the impact of a specimen having high parameter values preceding a specimen with low parameter values. This testing also serves substantiate the modified NRBC carryover claim for the updated DxH 800.	Class II Special Controls Guidance Section 12 - Carryover	Standards Documents • Validation, Verification, and Quality Assurance of Automated Hematology Analyzers, Approved Standard - 2nd Edition; June 2010; CLSI H26-A2 (FDA Standards Recognition # 7-210) Reference Documents • Guidelines for the evaluation of blood cell analyzers including those used for differential leukocyte and reticulocyte counting and cell marker applications. International Council for Standardization in Haematology: prepared by the ICSH expert panel on cytometry. Clin Lab Haematol, 16(2):157-174, 1994.	Analysis of the data collected demonstrates that the updated DxH 800 meets the whole blood and body fluid carryover performance requirements (within acceptance limits), for the parameters measured.

Study	Testing Approach	FDA Guidance Documents	Standards / References	510(k) Testing Summary
Specimens Anticoagulant	Testing was performed on the updated DxH 800 to demonstrate equivalency of results for whole blood specimens collected into K_2 and K_3EDTA and analyzed using the CBC, Differential and Retic analytical cycle.	Class II Special Controls Guidance Section 13 - Specimens	Standards Documents • Validation, Verification, and Quality Assurance of Automated Hematology Analyzers, Approved Standard - 2nd Edition; June 2010; CLSI H26-A2 (FDA Standards Recognition # 7-210) • Procedures for the Collection of Diagnostic Blood Specimens by Venipuncture; Approved Standard - Sixth Edition; October 2007; CLSI H3-A6 (FDA Standards Recognition # 7-201) • Procedures and Devices for the Collection of Diagnostic Capillary Blood Specimens; Approved Standard - Sixth Edition; September 2008; CLSI H04-A6 (FDA Standards Recognition # 7-203) • User Verification of Performance for Precision and Trueness Approved Guideline; Approved Guideline - Second Edition; June 2005; CLSI EP15-A2 (FDA Standards Recognition # 7-153) Reference Documents • Recommendations of the International Council for Standardization in Haematology for ethylenediaminetetraacetic acid anticoagulation of blood for blood cell counting and sizing. Am J Clin Path, 100(4)371-372, 1993.	Analysis of the data collected demonstrates that the updated DxH 800 meets performance requirements and provides comparable results, for all parameters reported, from specimens collected into K_2 and K_3EDTA.

Study	Testing Approach	FDA Guidance Documents	Standards / References	510(k) Testing Summary
Specimens Collection method	Testing was performed on the updated DxH 800 to demonstrate equivalency of results (within defined limits), for specimens collected by venipuncture and capillary collection methods and analyzed using the CBC, Differential and Retic analytical cycle.	Class II Special Controls Guidance Section 13 - Specimens	Standards Documents • Validation, Verification, and Quality Assurance of Automated Hematology Analyzers, Approved Standard - 2nd Edition; June 2010; CLSI H26-A2 (FDA Standards Recognition # 7-210) • Procedures for the Collection of Diagnostic Blood Specimens by Venipuncture; Approved Standard - Sixth Edition; October 2007; CLSI H3-A6 (FDA Standards Recognition # 7-201) • Procedures and Devices for the Collection of Diagnostic Capillary Blood Specimens; Approved Standard - Sixth Edition; September 2008; CLSI H04-A6 (FDA Standards Recognition # 7-203) • User Verification of Performance for Precision and Trueness Approved Guideline; Approved Guideline - Second Edition; June 2005; CLSI EP15-A2 (FDA Standards Recognition # 7-153)	Analysis of the data collected demonstrates that the updated DxH 800 meets the performance requirements and provides comparable results, for all parameters reported from specimens collected by venipuncture and capillary collection methods and analyzed using the CBC, Differential and Reticulocyte analytical cycle.
Specimens Stability	Testing was performed on the updated DxH 800 to demonstrate whole blood specimen stability. Testing was performed on whole blood specimens at various time intervals (long-term and short-term) and stored at refrigerated and room temperature. In addition testing was performed on pre-diluted specimens.	Class II Special Controls Guidance Section 13 - Specimens	Standards Documents None	Analysis of the data collected demonstrates that the updated DxH 800 meets the performance requirements and claims with respect to whole blood long term, short term and pre-dilute sample stability.

Study	Testing Approach	FDA Guidance Documents	Standards / References	510(k) Testing Summary
Reference Ranges	Confirmatory testing was performed on the updated DxH 800 to demonstrate comparability of whole blood reference ranges for an adult population to the ranges established for the predicate device.	Class II Special Controls Guidance Section 14 - Reference Values	Standards Documents • Defining, Establishing, and Verifying Reference Intervals in the Clinical Laboratory; Approved Guideline – Third Edition. CLSI C28-A3 (FDA Standards Recognition # 7-202)	The reference ranges established for the predicate DxH 800 are applicable for the updated DxH 800. The updated DxH 800 labeling will provide the reference ranges as currently presented in the predicate labeling.

9.0 **Conclusion:**

The data in the Premarket Notification on safety and effectiveness supports a finding that the UniCel® DxH 800 COULTER® Cellular Analysis System Update with software version 2.0 is substantially equivalent to the predicate device.

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.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

March 22, 2013

Beckman Coulter, Inc.
c/o Mr. Eric Grace
Senior Staff, Product Management
11800 SW 147th Avenue
Miami, Florida 33196-2500

Re: k120771
Trade/Device Name: UniCel® DxH 800 COULTER® Cellular Analysis System
Regulation Number: 21 CFR § 864.5220
Regulation Name: Automated differential cell counter
Regulatory Class: Class II
Product Code: GKZ
Dated: March 11, 2013
Received: March 14, 2013

Dear Mr. Grace:

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 Part 801); 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 regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 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 Small Manufacturers, International and Consumer Assistance 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,

Maria M. Chan -S

Maria M. Chan, Ph.D.
Director
Division of Immunology and Hematology Devices
Office of *In Vitro* Diagnostics and Radiological Health
Center for Devices and Radiological Health

Enclosure

Indication for Use

510(k) Number (if known): K120771

Device Name: UniCel® DxH 800 COULTER® Cellular Analysis System

Indication for Use:

The UniCel® DxH 800 Analyzer is a quantitative multi-parameter, automated hematology analyzer for *in vitro* diagnostic use in screening patient populations found in clinical laboratories.

The UniCel® DxH 800 Analyzer identifies and enumerates the parameters indicated below on the following sample types:

- Whole Blood (Venous and Capillary)
  - WBC, RBC, HGB, HCT, MCV, MCH, MCHC, RDW, RDW-SD, PLT, MPV, NE%, NE#, LY%, LY#, MO%, MO#, EO%, EO#, BA%, BA#, NRBC%, NRBC#, RET%, RET#, MRV, IRF
- Pre-Diluted Whole Blood (Venous and Capillary)
  - WBC, RBC, HGB, HCT, MCV, MCH, MCHC, RDW, RDW-SD, PLT, MPV
- Body Fluids (cerebrospinal, serous and synovial)
  - TNC and RBC

Prescription Use ___X___ And/Or Over the Counter Use ____.
(21 CFR Part 801 Subpart D) (21 CFR Part 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE; CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Device Evaluation and Safety (OIVD)

Leonthena R. Carrington -S

Division Sign-Off
Office of In Vitro Diagnostic Device
Evaluation and Safety

510(k) K120771