April 16, 2020

Beckman Coulter
Samy Puccio
Staff Regulatory Affair Specialist
11800 SW 147th Ave
Miami, Florida 33196-2500

Re: K193124
Trade/Device Name: Unicel DxH 800 Coulter Cellular Analysis System, Unicel DxH 800 Coulter Cellular Analysis System with Early Sepsis Indicator Application
Regulation Number: 21 CFR 864.5220
Regulation Name: Automated Differential Cell Counter
Regulatory Class: Class II
Product Code: GKZ, QFS
Dated: November 7, 2019
Received: November 12, 2019

Dear Samy Puccio:

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. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. 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 and Part 809); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

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 https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Takeesha Taylor-Bell
Chief
Division of Immunology and Hematology Devices
OHT7: Office of In Vitro Diagnostics
and Radiological Health
Office of Product Evaluation and Quality
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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K193124

Device Name
Unicel DxH 800 Coulter Cellular Analysis System
Unicel DxH 800 Coulter Cellular Analysis System with Early Sepsis Indicator Application

Indications for Use *(Describe)*
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

The Unicel DxH 800 Coulter Cellular Analysis System with Early Sepsis Indicator Application
is the quantitative measurement of Monocyte Distribution Width (MDW). The Early Sepsis Indicator is intended for use with adult patients presenting to the emergency department, on whom a white cell differential test has been ordered.

MDW is measured from a (K2EDTA) whole-blood venous sample within 2 hours of collection. MDW values greater than 20.0 together with other laboratory findings and clinical information, aids in identifying patients with sepsis or at increased risk of developing sepsis within the first 12 hours of hospital admission.

MDW values greater than 20.0 should be interpreted in association with other clinical information and diagnostic testing, as a proportion of patients without sepsis may have an elevated MDW value at baseline.

MDW values less than or equal to 20.0 cannot rule out sepsis or the development of sepsis within 12 hours of hospital admission. The Early Sepsis Indicator should not be used as the sole basis to determine the absence of sepsis.

The predictive value of the Early Sepsis Indicator for identifying sepsis in patients with hematological abnormalities has not been established.

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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

510(k) Summary for
Unicel DxH 800 Cellular Analysis System

510(k) Owner / Submitter Information

Company Name: Beckman Coulter Inc.
Address: 11800 SW 147th Ave., Miami, FL 33196
Phone #: (305) 380-4509
Fax #: (786) 639-4156
Contact Person: Samy Puccio
Email Address: spuccio@beckman.com

Date Submitted:

December 19, 2019

Device Information

Trade Name: Unicel DxH 800 Coulter Cellular Analysis System,
Unicel DxH 800 Coulter Cellular Analysis System with Early Sepsis Indicator Application
Common Name: DxH 800
Classification Name: Automated differential cell counter (21 CFR 864.5220)
Classification Name: Device to detect and measure non-microbial analyte(s) in human clinical specimens to aid in assessment of patients with suspected sepsis (21 CFR 866.3215)
Classification: Class II (Special Controls)
Product Code: GKZ, QFS
Panel: Hematology, Microbiology

Predicate Device Information

Predicate Product	510(k) Number	Date Cleared	Classification	21 CFR	Product Code
Unicel DxH 800 Coulter Cellular Analysis System	K140911	Sept 5, 2014	Class II	864.5220	GKZ
Unicel DxH 800 Coulter Cellular Analysis System with Early Sepsis Indicator Application	K181599	Mar 18, 2019	Class II	864.5220 866.3215	GKZ QFS

UniCel DxH 800 Coulter Cellular Analysis System and Unicel DxH 800 Coulter Cellular Analysis System with Early Sepsis Indicator Application

This 510(k) submission is for the UniCel DxH 800 Coulter Cellular Analysis System (DxH 800) with software version 3.9.0.

The Early Sepsis Indicator (ESI) requires the use of the UniCel DxH 800 Coulter Cellular Analysis System (DxH 800) and its reagents, controls and calibrators last cleared under 510(k) K140911.

The DxH 800 System is a quantitative, automated hematology analyzer designed for in vitro diagnostic use in screening patient populations by clinical laboratories. The system provides a Complete Blood Count (CBC), Leukocyte 5 Part Differential (Diff), Reticulocyte (Retic), Nucleated Red Blood Cell (NRBC) on whole blood, as well as, Total Nucleated Count (TNC), and Red Cell Count (RBC) on Body Fluids (cerebrospinal, serous and synovial). The DxH 800 also includes the Monocyte Distribution Width (MDW) parameter shown to aid in the early detection of Sepsis in emergency room adult patients.

The system consists of two primary components, the workstation and the DxH 800 analyzer as shown in Figure 1. DxH 800 System Configuration. The primary function of the DxH 800 analyzer is to process samples and provide results to the workstation. The primary functions of the workstation are: user interface, system control, results processing and storage and external communications. The analyzer runs embedded code and the workstation runs Microsoft Windows 7 Operating System (OS).

Optionally, the workstation can be connected to:

- A printer for creating reports;
- A Laboratory Information System (LIS) for receiving test orders and releasing results; and
- Pro-Service Remote Management System (RMS) which provides secure access to the DxH800 workstation for BCI Service Personnel to perform troubleshooting, system monitoring and for assisting customers.

Design Change Description:

This modification to the DxH 800 is being implemented as part of corrective action for a field action initiated by Beckman Coulter (BEC) in July 2018. The field action was issued on the DxH instruments to notify customers that BEC received and confirmed reports of sporadic erroneously elevated platelet results without flags or system messages on some software versions of the UniCel DxH 800/600.

As part of an initial corrective action, BEC developed a software patch that contains an additional criterion to an existing algorithm flag in the software, alerting the user of a suspect PLT finding and to review the result. Upon further investigation, a root cause

was identified as the sweep flow disruption that may occur following the "Clear RBC Apertures" procedure. Customers were informed to discontinue using this procedure and discontinue use of the analyzer if the instrument had a clogged aperture that would not clear. Customers were then instructed to contact Beckman Coulter Customer Support Center and request service.

The modification prompting a new submission is an update to the DxH 800 software included in version 3.9.0 and contains the following changes:

1. The addition of a "T50" criteria to an existing rule (154) to detect erroneously elevated platelet results caused by sweep flow obstructions. The system message (PLT Inter:Debris) is displayed and the "R" (review) flag is added to the platelet results directing the user to review per instructions provided in the IFU.

2. Disable Clear RBC Aperture Update (The software patch to address field action FA-33718-2). A software change to internal software table values to display an error when user selects to execute the Clear RBC Apertures cycle (preventing the hardware execution of the procedure).

3. Strengthen cybersecurity. This includes enabling whitelisting to prevent unauthorized software from being installed, enabling Windows Firewall on all network cards to prevent unauthorized network traffic and a user option to secure data by encrypting the hard drive.

4. Addition of Automated VCSn Optimization feature. A software change to verify the Latron CP-X control (beads) recovers within the limits and optimize the calibration factor of the VCSn module. The adjustment occurs only during the Daily Shutdown cycle and uses the ratio of five successful Latron CP-X runs to compute the calibration factor needed.

Intended Use/Indications for Use:

Unicel DxH 800 Coulter Cellular Analysis System (K140911)

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.

Unicel DxH 800 Cellular Analysis System with Early Sepsis Indicator Application (K181599)

The UniCel DxH 800 Coulter Cellular Analysis System with Early Sepsis Indicator Application is the quantitative measurement of Monocyte Distribution Width (MDW). The Early Sepsis Indicator is intended for use with adult patients presenting to the emergency department, on whom a white cell differential test has been ordered.

MDW is measured from a (K2EDTA) whole-blood venous sample within 2 hours of collection. MDW values greater than 20.0 together with other laboratory findings and clinical information, aids in identifying patients with sepsis or at increased risk of developing sepsis within the first 12 hours of hospital admission.
MDW values greater than 20.0 should be interpreted in association with other clinical information and diagnostic testing, as a proportion of patients without sepsis may have an elevated MDW value at baseline.

MDW values less than or equal to 20.0 cannot rule out sepsis or the development of sepsis within 12 hours of hospital admission. The Early Sepsis Indicator should not be used as the sole basis to determine the absence of sepsis.

The predictive value of the Early Sepsis Indicator for identifying sepsis in patients with hematological abnormalities has not been established.

Comparison to Predicate:

The design changes applied to the DxH 800 serve as additional mitigations to existing risk control measures to the potential failure mode identified in the root cause analysis of the field action that initiated these changes.

These design changes do not impact the intended use or performance claims of the DxH 800.

Device Comparison Table:

Characteristic	UniCel DxH 800 Coulter Cellular Analysis System (K140911) and, Unicel DxH 800 Coulter Cellular Analysis System with Early Sepsis Indicator Application (K181599)	Proposed Device
Intended Use and Function	**K181599** The UniCel DxH 800 Coulter Cellular Analysis System with Early Sepsis Indicator Application is the quantitative measurement of Monocyte Distribution Width (MDW). The Early Sepsis Indicator is intended for use with adult patients presenting to the emergency department, on whom a white cell differential test has been ordered. MDW is measured from a (K2EDTA) whole-blood venous sample within 2 hours of collection. MDW values greater than 20.0 together with other laboratory findings and clinical information, aids in identifying patients with sepsis or at increased risk of developing sepsis within the first 12 hours of hospital admission. MDW values greater than 20.0 should be interpreted in association with other clinical information and diagnostic testing, as a proportion of patients without sepsis may have an elevated MDW value at baseline. MDW values less than or equal to 20.0 cannot rule out sepsis or the development of sepsis within 12 hours of hospital admission. The Early Sepsis Indicator should not be used as the sole basis to determine the absence of sepsis. The predictive value of the Early Sepsis Indicator for identifying sepsis in patients with hematological abnormalities has not been established. **K140911** 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	Same Same

Characteristic	UniCel DxH 800 Coulter Cellular Analysis System (K140911) and, Unicel DxH 800 Coulter Cellular Analysis System with Early Sepsis Indicator Application (K181599)	Proposed Device
	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	Aperture impedance (Coulter® Principle)	Same
Hemoglobin	Spectrophotometric	Same
WBC Differential, Reticulocytes, NRBC, MDW	VCSn Technology using: • Aperture impedance (DC) • Conductivity (RF) • Laser Light Scatter (Multiple • angles) • Laser Light Absorbance	Same
Reagents		
Analysis Reagents	COULTER DxH Diluent COULTER DxH Diff Pack COULTER DxH Cell Lyse COULTER DxH Retic Pack COULTER DxH Cleaner	Same
Quality Control & Calibrator	COULTER 6C Cell Control Coulter 6C Plus 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
Pre-Analytic Features		

Characteristic	UniCel DxH 800 Coulter Cellular Analysis System (K140911) and, Unicel DxH 800 Coulter Cellular Analysis System with Early Sepsis Indicator Application (K181599)	Proposed Device
System configuration	PC based workstation running Microsoft Windows XP application specific software Handheld Barcode Scanner Printer	Same
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
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
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
Sample Processing		
Aspiration Pathway	Single sampling probe and common aspiration pathway used for all sample presentation modes.	Same
Sample aspiration volume	Automatic, cap-piercing: 165 µL Single tube - open-vial and cap pierce:165 µL Pre-dilute 165 µL - fixed ratio of 1 in 5 dilution of blood with diluent	Same
Throughput	For automatic mode: • CBC at 100 specimens/hr. • CBC and Differential at 100 specimens/hr. • CBC and Differential with NRBC at 90 specimens/hr. • Retic at 45 specimens/hr.	Same
Data reporting	Workstation display graphics, hardcopy printing and transmission to Laboratory Information System (LIS)	Same
System Control and Software		
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	Same

Characteristic	UniCel DxH 800 Coulter Cellular Analysis System (K140911) and, Unicel DxH 800 Coulter Cellular Analysis System with Early Sepsis Indicator Application (K181599)	Proposed Device
	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 collectionSingle sampling probe and common aspiration pathway used for all sample presentation modes.	
Software Version	Version 3.8.0	Version 3.9.0 • Includes the additional criteria for T50 Flag • Disable Clear RBC Aperture • Strengthened Cybersecurity • Automated VCSn Optimization.

Summary of Performance Testing:

To demonstrate substantially equivalence (SE), the following design performance verification analyses were performed and evaluated:

1. Carryover
2. Linearity
3. Precision
4. Method Comparison

Design Control Activities

The design development and verification/validation of the device modification have been performed under design control. The design control activities were based on risk analysis, and acceptance criteria were set to maintain the efficiency and safety of the device. Testing included design software verification testing, human factors and installation testing.

Substantial Equivalence Conclusion to Demonstrate Safety, Effectiveness & Equivalent Performance to Predicate:

The updates to the DxH 800 that are the subject of this submission, do not change the intended use, nor add or delete a contraindication for the device. The changes do not alter the device control mechanism, operating principle, energy type, environmental specification, ergonomics of the user interface, dimensional specifications, nor packaging.

The device does not have expiration dating nor is it subject to sterilization.

In summary, it can be concluded that the updated DxH 800, as described in this submission is substantially equivalent in terms of safety and effectiveness 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.