DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
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September 5, 2014

BECKMAN COULTER, INC.
C/O MR. BRENT LEMBERG
STAFF REGULATORY AFFAIRS SPECIALIST
11800 SW 147TH AVE.
MIAMI FL 33196

Re: K140911
Trade/Device Name: UniCel DxH 800 and DxH Slidemaker Stainer Coulter Cellular Analysis System
Regulation Number: 21 CFR 864.5220
Regulation Name: Automated differential cell counter
Regulatory Class: II
Product Code: GKZ
Dated: August 4, 2014
Received: August 6, 2014

Dear Mr. Lemberg:

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,

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

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)*

Device Name
UniCel® DxH 800 Coulter® Cellular Analysis System

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

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)

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Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

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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)*

Device Name
UniCel® DxH Slidemaker Stainer Coulter® Cellular Analysis System

Indications for Use *(Describe)*
The DxH Slidemaker Stainer is a fully automated slide preparation and staining device that aspirates a whole-blood sample, smears a blood film on a clean microscope slide, and delivers a variety of fixatives, stains, buffers, and rinse solutions to that blood smear.

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)

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Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

Maria M. Chan -S

Section 5	510(k) Summary

510(k) Summary for
UniCel® DxH 800 Coulter® Cellular Analysis System and
UniCel DxH Slidemaker Stainer Coulter® Cellular Analysis System

510(k) Owner / Submitter Information

Name: Beckman Coulter Inc.
Address: 11800 SW 147th Ave., Miami, FL 33196
Phone #: (305) 380-4509
Fax #: (305) 380-4344
Contact Person: Brent Lemberg
Email Address: blemberg@beckman.com
Date Submitted: April 10, 2014

Device Information

Trade Name: **UniCel® DxH 800 Coulter® Cellular Analysis System**
Common Name: DxH 800
Classification Name: Automated differential cell counter (21 CFR 864.5220)
Classification: Class II
Product Code: GKZ
Panel: Hematology

Trade Name: **UniCel® DxH Slidemaker Stainer Coulter® Cellular Analysis System**
Common Name: DxH SMS
Classification Name: Automated differential cell counter (21 CFR 864.5220)
Classification: Class II
Product Code: GKZ
Panel: Hematology

Predicate Device Information

Predicate Product	510(k) Number	Date Cleared	Classification	21 CFR	Product Code
UniCel® DxH 800 Coulter® Cellular Analysis System	K120771	March 22, 2013	Class II	864.5220	GKZ
Manually prepared blood films per the manual wedge-pull film technique as described in CLSI H20-A2, Reference Leukocyte (WBC) Differential Count (Proportional) and Evaluation of Instrument Methods; Approved Standard – Second Edition	N/A	N/A	N/A	N/A	N/A

Device Description

The DxH 800 and DxH SMS form a family of integrated and interactive modular products that are scalable to meet the specific laboratory workflow and workload needs. Currently these products are offered as stand-alone devices only.

- **DxH 800:** 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 Five-part Differential (Diff), Reticulocyte (RET), Nucleated Red Blood Cell (NRBC) on whole blood, Total Nucleated Count (TNC) and Red Blood Cell Count (RBC) on Body Fluids (cerebrospinal, serous and synovial)

- **DxH SMS**: The DxH Slidemaker Stainer is a fully automated slide preparation and staining device that aspirates a whole-blood sample, smears a blood film on a clean microscope slide, and delivers a variety of fixatives, stains, buffers, and rinse solutions to that blood smear.

The upgrade of these devices with software v3.0 will allow for these stand-alone devices to be configured into five workcell configurations through physical and virtual connections. Physically, the instruments are connected via hardware and the virtual connection is accomplished by means of the new control system software that provides integrated process control, data consolidation and sample transport to the various instruments in the workcell in order to facilitate and improve laboratory efficiency. This will yield a total of seven product configurations, including:

- Stand-alone DxH 800 with software v3.0
- Stand-alone DxH SMS with software v3.0
- Five customizable workcell configurations comprised of DxH 800 and DxH SMS with software v3.0
    - DxH 801 – one DxH 800 + one DxH SMS
    - DxH 1600 – two DxH 800
    - DxH 1601 – two DxH 800 + one DxH SMS
    - DxH 2400 – three DxH 800
    - DxH 2401 – three DxH 800 + one DxH SMS

These workcell configurations allow for increased system efficiencies through workload balancing between available instruments within the workcell, and automated pass through processing of selected slide preparation and stain test orders.

Intended Use:

DxH 800 Indications 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

DxH SMS Indications for Use:

The DxH Slidemaker Stainer is a fully automated slide preparation and staining device that aspirates a whole-blood sample, smears a blood film on a clean microscope slide, and delivers a variety of fixatives, stains, buffers, and rinse solutions to that blood smear.

Technological Characteristics Comparisons to Predicate

DxH 800 Device Comparison Table:

Similarities		
Characteristic	**Predicate** **UniCel DxH 800 Software 2.0**	**Device** **UniCel DxH 800 Software 3.0**
Indications 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) o 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) o WBC, RBC, HGB, HCT, MCV, MCH, MCHC, RDW, RDW-SD, PLT, MPV ▪ Body Fluids (cerebrospinal, serous and synovial) o TNC and RBC	Same as predicate
Sampling Mechanism	• Single aspiration probe used for all sampling. • Single tube presentation – open and closed vial sampling – specimen manually mixed • Automated cassette presentation – closed vial sampling from five- position cassette accepting a variety of defined specimen tubes. Cassette containing specimens mixed prior to starting sampling and between specimens. • Maximum initial load capacity 20 cassettes - System will continuously process cassettes as added.	Each DxH 800 in the workcell utilizes the same sampling mechanism as the predicate.

Similarities		
Characteristic	**Predicate** **UniCel DxH 800 Software 2.0**	**Device** **UniCel DxH 800 Software 3.0**
Mechanisms for Processing	Mechanisms to achieve process of : o automated cassette transportation and specimen mixing (by rocking) o sample aspiration o sample preparation o sample and reagent presentation to analytical modules o sample analysis o raw data collection o algorithmic processing o data reporting Specimen tube is in upright (cap up) position for closed vial sampling Cassette transportation by magnetic drive allowing multi-directional moves and capability to return cassette to sampling position for repeat / reflex testing	Each DxH 800 in the workcell utilizes the same mechanisms for processing as the predicate except: In a connected configuration, specimen transportation capability between multiple DxH 800 analyzers. Repeat / reflex testing can be done on different analyzer than initial testing.
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
Data Reporting	Workstation display graphics, hardcopy printing and transmission to host Laboratory Information System (LIS)	Same as Predicate

Similarities		
Characteristic	**Predicate** **UniCel DxH 800 Software 2.0**	**Device** **UniCel DxH 800 Software 3.0**

Performance Characteristics	The performance characteristics provided for:
	• Comparison of Measurement Procedures
	  • Whole Blood – CBC
	  • Whole Blood - Reticulocyte
	  • Whole Blood – Differential
	  • Whole Blood – NRBC
	  • Body Fluids
	• Imprecision
	  • Whole Blood CBC, DIFF, Retic
	  • Prediluted Blood
	  • CSF, Serous, Synovial Body Fluid
	• Linearity
	• Carryover (High to Low)
	  • Whole Blood CBC, DIFF, Retic, NRBC, Body Fluids
		Same as predicate with no changes to stated performance characteristics

Operating Principles	Method of sample analysis	Same as predicate
Consumables	Reagents, controls, and calibrators utilized by the system	Same as predicate

Differences		
Characteristic	**Predicate** **UniCel DxH 800 Software 2.0**	**Device** **UniCel DxH 800 Software 3.0**
System Configuration	▪ Workcell configuration of one DxH 800 (stand-alone) ▪ Bench top ▪ 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	Individual analyzers are same as predicate except analyzers can be connected creating multiple workcell configurations (up to three DxH 800s and up to 1 DxH SMS) Workcell configurations available only on a floor stand, not on a bench top. PC based workstation running Microsoft Windows 7 application specific software
Workstation	Software functionality to control sample processing as well as patient and control data management	Each DxH 800 in the workcell utilizes the same functionality as the predicate except one system manager controls sample processing and management for up to three DxH 800s plus one DxH SMS

DxH SMS Device Comparison Table:

Characteristic	Predicate Manual Method (H20-A2, Reference Leukocyte (WBC) Differential Count (Proportional) and Evaluation of Instrumental Methods; Approved Standard	Device UniCel DxH Slidemaker Stainer Software 3.0
Indications for use	Manual preparation of whole blood smears on microscopic slides using a variety of fixatives, stains, buffers, and rinse solutions.	The DxH Slidemaker Stainer is a fully automated slide preparation and staining device that aspirates a whole blood sample, smears a blood film on a clean microscope slide, and delivers a variety of fixatives, stains, buffers, and rinse solutions to that blood smear.
Device Classification & Product Code	Not applicable	21 CFR 864.5220 Automated Cell Counter, GKZ
Manufacturer	Not applicable	Beckman Coulter
Specimen Collection	Whole venous blood in EDTA	Same as predicate
Blood Film Preparation	Manually prepared by technician	Automatically prepared by DxH SMS
Blood Film Requirements	Section 6.3.1 of CLSI H20-A2	Same as predicate

Summary of DxH 800 Performance Testing

Study	Testing Approach	FDA Guidance Documents	Standards/ References	Testing Results
Electromagnetic Compatibility (EMC) Interference	Verify that the EMC interference of individual DxH 800 instruments is not impacted when configured in a workcell configuration.	None	None	The analysis demonstrated that it is unlikely that EMC interference would be increased in the connected DxH workcell as compared to a stand-alone DxH 800.
Vibration Testing	Verify that vibration introduced from interconnection of multiple DxH 800 and/or DxH SMS instruments in a workcell configuration does not impact the performance of the individual DxH 800 instruments.	None	None	The analysis demonstrated that it is unlikely that vibration in the connected DxH workcell would impact performance.
Measurement Procedure Comparison: Whole Blood and Body Fluids	To evaluate bias between the test instruments versus the predicate DxH 800 v2.0.	Special Controls Guidance Document: Premarket Notifications for Automated Differential Cell Counters for Immature or Abnormal Blood Cells - Accuracy (Section 8)	• Validation, Verification, and Quality Assurance of Automated Hematology Analyzers, Approved Standard – 2nd Edition; June 2010; CLSI H26-A2; FDA Standards Recognition # 7-210 • Measurement Procedure Comparison and Bias Estimation Using Patient Samples; Approved Guideline – Third Edition: CLSI EP9-A3; FDA Standards Recognition # 7-245	Analysis of the data collected demonstrates that the DxH 800 v3.0 meets the performance requirements for whole blood and body fluids bias when compared to the predicate device.
Imprecision (Repeatability): Whole Blood and Body Fluids	To verify the imprecision (repeatability) of the DxH 800 meets performance specifications.	Special Controls Guidance Document: Premarket Notifications for Automated Differential Cell Counters for Immature or Abnormal Blood Cells - Precision (Section 9)	• Validation, Verification, and Quality Assurance of Automated Hematology Analyzers, Approved Standard – 2nd Edition; June 2010; CLSI H26-A2; FDA Standards Recognition # 7-210	Analysis of the data collected demonstrates that the DxH 800 v3.0 meets performance requirements for repeatability for whole blood and body fluids.

Study	Testing Approach	FDA Guidance Documents	Standards/ References	Testing Results
Limits (LoB, LLoD, LLoQ)	To verify that the DxH 800 meets the performance requirements for Limit of Blank (LoB), Lower Limit of Detection (LLoD), Lower Limit of Quantitation (LLoQ).	None	• 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 Detection Capability for Clinical Laboratory Measurement Procedures; Approved Guideline – Second Edition; CLSI EP17-A2; FDA Standards Recognition #7-233	Analysis of the data collected demonstrates that the DxH 800 v3.0 meets the performance requirements for LoB, LLoD, and LLoQ in whole blood and body fluids.
Linearity: Whole Blood and Body Fluids	To verify linearity of WBC, RBC, Hgb and Plt parameters for whole blood and TNC and BF-RBC parameters for body fluids.	Special Controls Guidance Document: Premarket Notifications for Automated Differential Cell Counters for Immature or Abnormal Blood Cells - Linearity (Section 11)	• 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 Procedures: A Statistical Approach; Approved Guideline; April 2003. CLSI EP06-A; FDA Standards Recognition #7-193	Analysis of the data collected demonstrates that the DxH 800 v3.0 meets the linearity performance requirements for whole blood and body fluids.
Carryover: Whole Blood and Body Fluid	To verify carryover for whole blood and body fluids on the DxH 800 meets performance specifications.	Special Controls Guidance Document: Premarket Notifications for Automated Differential Cell Counters for Immature or Abnormal Blood Cells - Carryover (Section 12)	• Validation, Verification, and Quality Assurance of Automated Hematology Analyzers, Approved Standard - 2nd Edition; June 2010; CLSI H26-A2; FDA Standards Recognition #7-210	Analysis of the data collected demonstrates that the DxH 800 v3.0 meets the whole blood and body fluid carryover performance requirements.

Summary of DxH SMS Performance Testing:

Study	Testing Approach	FDA Guidance Documents	Standards/ References	Testing Results
Slide Quality	To verify that the DxH SMS produces slides that meet the slide quality specifications.	None	CLSI H20-A2, Reference Leukocyte (WBC) Differential Count (Proportional) and Evaluation of Instrumental Methods, Approved Standard – Second Edition; FDA Standards Recognition #7-165	The DxH SMS meets the performance requirements for slide quality.
Carryover	To verify that the Carryover of the DxH SMS meets the performance specifications.	None	None	Analysis of the data collected demonstrates that the DxH SMS meets the performance requirements for blood smear carryover.

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

The updates to the DxH 800 and DxH SMS with software v3.0 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.

The conclusions drawn from the performance testing discussed above demonstrate that the device is as safe, as effective, and meets the performance acceptance criteria.

In summary, the updated DxH 800 and DxH SMS with software v3.0, as described in this submission are substantially equivalent in terms of safety and effectiveness to their predicate device and reference method, respectively.

- The UniCel DxH 800 Coulter Cellular Analysis System v3.0 is substantially equivalent to the UniCel DxH 800 Coulter Cellular Analysis System v2.0 manufactured by Beckman Coulter.
- The UniCel DxH Slidemaker Stainer Coulter Cellular Analysis System v3.0 is substantially equivalent to manually prepared blood films per the manual wedge-pull film technique as described in CLSI H20-A2, Reference Leukocyte (WBC) Differential Count (Proportional) and Evaluation of Instrumental Methods; Approved Standard

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.