DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

November 29, 2016

Beckman Coulter, Inc.
Ms. Nancy Nadler
Director, Regulatory Affairs
11800 SW 147th Avenue
Miami, Florida 33196-2500

Re: K162414
Trade Name: UniCel® DxH Slidemaker Stainer Coulter® Cellular Analysis System
Regulation Number: 21 CFR 864.5220
Regulation Name: Automated Differential Cell Counter
Regulatory Class: Class II
Product Code: GKZ
Dated: October 31, 2016
Received: November 1, 2016

Dear Ms. Nadler:

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 regulation (21 CFR Part 801), 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" (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 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,

Leonthena R. Carrington -S

Leonthena R. Carrington, MS, MBA, MT(ASCP)
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)*
K162414

Device Name
UniCel DxH Slidemaker Stainer Coulter Cellular Analysis System

Indications for Use *(Describe)*
The DxH Slidemaker Stainer (SMS) 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)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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510(k) Summary for
Special 510(k) for the
UniCel DxH Slidemaker Stainer Coulter® Cellular Analysis System

510(k) Owner / Submitter Information

Company Name: Beckman Coulter Inc.
Address: 11800 SW 147th Ave., Miami, FL 33196
Phone #: (305) 380-4191
Fax #: (786) 639-4191
Contact Person: Nancy Nadler
Email Address: nancy.nadler@beckmancoulter.com

Date Submitted:

August 26, 2016

Device Information

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 and Pathology Devices Panel

Predicate Device Information

Predicate Product	510(k) Number	Date Cleared	Classification	21 CFR	Product Code
UniCel® DxH SMS Coulter® Cellular Analysis System	K140911	September 5, 2014	Class II	864.5220	GKZ

Device Description

The DxH Slidemaker Stainer (SMS) 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 DxH SMS consists of a slidemaking module, a slidestaining module, and a specimen transport module precisely integrated to provide process control, slidemaking and staining,

and cassette or single-tube delivery of specimens. The DxH SMS processes patient specimens and sends status data to the System Manager.

The System Manager:

- Controls processes, such as making and staining blood smears, and diagnostic procedures.
- Manages data, such as test ordering, LIS interface, and logging.

The System Manager resides on a Personal Computer (PC) based workstation running system application specific software. The PC is connected to the DxH SMS via an Ethernet connection. The System Manager provides data management and storage, provides test order management, quality control functionality, diagnostics and maintenance procedures. User interaction is provided via touch screen, keyboard and mouse.

Design Change Description:

This modification to the DxH SMS is being implemented as part of the corrective action for a field action initiated by Beckman Coulter (BEC) in early August 2016. The field action was issued on the DxH SMS to notify customers that BEC received and confirmed a report of a fire within the Stainer module of a customer's instrument. BEC instructed customers to immediately discontinue use of the Stainer module.

As part of the corrective actions, BEC had developed additional risk control measures for the device to mitigate the potential failure modes associated with the reported fire on the DxH SMS.

Intended Use/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.

Comparison to Predicate:

The design changes applied to the DxH SMS serve as additional risk control measures to mitigate each of the potential failure modes 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 SMS.

Device Comparison Table:

Characteristic	UniCel DxH Slidemaker Stainer (K140911, Predicate)	Proposed Device
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.	Same
Device Classification & Product Code	21 CFR 864.5220 Automated Cell Counter, GKZ	Same
Manufacturer	Beckman Coulter	Same
Specimen Collection	Whole venous blood in EDTA	Same
Blood Film Preparation	Automatically prepared by DxH SMS	Same
Blood Film Requirements	Section 6.3.1 of CLSI H20-A2	Same

Summary of DxH SMS Performance Testing:

Performance testing is not required. Testing was limited to design and software verification testing.

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 verification testing, temperature testing, and installation testing.

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

The updates to the DxH SMS 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, the updated DxH SMS, 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.