K081930

DEC 19 2008

510(k) Summary
UniCel® DxH 800 Coulter® Cellular Analysis System

1.0 **Submitted By:**

Lourdes Coba
Staff Regulatory Affairs Specialist
Beckman Coulter, Inc.
11800 SW 147 Avenue, M/C: 31-B06
Miami, Florida 33196-2500
Telephone: (305) 380-4079
FAX: (305) 380-4344

2.0 **Date Submitted:**

July 3, 2008

3.0 **Device Name(s):**

3.1 **Proprietary Names**

UniCel® DxH 800 Coulter® Cellular Analysis System

3.2 **Classification Name**

Automated differential cell counter
(21 CFR § 864.5220)

4.0 **Predicate Devices:**

Candidate	Predicates	Manufacturer	Docket Number
UniCel® DxH 800 Coulter® Cellular Analysis System	COULTER® LH 750 Hematology Analyzer	Beckman Coulter, Inc.	K011342
	COULTER® LH 780 Hematology Analyzer	Beckman Coulter, Inc.	K061616

5.0 Description:

The UniCel® DxH 800 Coulter® Cellular Analysis System (DxH 800 System) is intended for In Vitro Diagnostic Use in clinical laboratories. The DxH 800 System provides automated complete blood count, leukocyte differential, NRBC enumeration and reticulocyte analysis as well as an automated method for enumeration of RBCs and TNCs in body fluids.

The purpose of the DxH 800 System is intended to separate the normal patient, with all normal system-generated parameters, from the patient who needs 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 instrument system is comprised of the analyzer and a suite of analytical reagents that allow for simultaneous quantitative determination of hematological parameters through the use of impedance, RF, flow cytometric light scatter, spectrophotometry, and supravital staining methodologies. Additional reagents provide system cleaning and quality control and calibration.

6.0 Intended Use:

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
- a Total Nucleated Count (TNC) and Red Cell Count (RBC) on Body Fluids (cerebrospinal, serous and synovial) (BF)

7.0 Comparison to Predicate(s):

Characteristic	COULTER® LH 750 (Predicate)	COULTER® LH 780 (Predicate)	UniCel® DxH 800
Intended Use	The COULTER LH 750 Hematology Analyzer is a quantitative, automated hematology analyzer and leukocyte differential counter For In Vitro Diagnostic Use in clinical laboratories. The COULTER LH 750 Hematology Analyzer provides automated Reticulocyte analysis and enumeration of nucleated red blood cells (NRBCs) as well as an automated method for enumeration of RBCs and WBCs in body fluids.	The COULTER LH 780 Hematology Analyzer is a quantitative, automated hematology analyzer and leukocyte differential counter For In Vitro Diagnostic Use in clinical laboratories. The COULTER LH 780 Hematology Analyzer provides automated Reticulocyte analysis and enumeration of nucleated red blood cells (NRBCs) as well as an automated method for enumeration of RBCs and WBCs in body fluids.	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 ▪ a Total Nucleated Count (TNC) and Red Cell Count (RBC) on Body Fluids (cerebrospinal, serous and synovial) (BF)
Parameters IVD	WBC, RBC, Hgb, Hct, MCV, MCH, MCHC, RDW, Plt, MPV, LY%, MO%, NE%, EO%, BA%, LY#, MO#, NE#, EO#, BA#, NRBC%, NRBC#, RET%, RET#, IRF, & MRV.	WBC, RBC, Hgb, Hct, MCV, MCH, MCHC, RDW, RDW-SD, Plt, MPV, LY%, MO%, NE%, EO%, BA%, LY#, MO#, NE#, EO#, BA#, NRBC%, NRBC#, RET%, RET#, IRF, & MRV.	Same as LH 750 / 780 except WBC reported as Total Nucleated Cell Count (TNC) in body fluids

Characteristic	COULTER® LH 750 (Predicate)	COULTER® LH 780 (Predicate)	UniCel® DxH 800
Quality Control Techniques	Daily Instruments Check, Commercial Controls, Delta Checks, Patient Controls, XB Analysis, & IQAP.	Daily Instruments Check, Commercial Controls, Delta Checks, Patient Controls, XB Analysis, & IQAP, Extended QC & XM Analysis	Same as LH 750 / 780
Quality Controls & Calibrator	COULTER® 5C® Cell Control COULTER® Latron™ Primer and Latron Control COULTER® RETIC-C™ Cell Control COULTER® LIN-C® Linearity Control COULTER® S-CAL® calibrator kit	COULTER® 5C® Cell Control COULTER® Latron™ Primer and Latron Control COULTER® RETIC-C™ Cell Control COULTER® LIN-C® Linearity Control COULTER® S-CAL® Calibrator Kit	COULTER® 6C Cell Control (pending clearance K081822) COULTER® Latron™ CP-X Control (same product as Latron Control) COULTER® RETIC-X Cell Control (same product as Retic-C) COULTER® LIN-X control (pending clearance K081641) COULTER® S-CAL® Calibrator kit COULTER® Body Fluids Control (pending 510k submission)
Analysis Reagents	COULTER® LH Series Diluent COULTER® Isoton 4 Diluent COULTER® LH Series Pak COULTER® LH Series RETIC Pak COULTER® Lyse S® III lytic agent COULTER® Lyse S® 4 lytic agent	COULTER® LH Series Diluent COULTER® Isoton 4 Diluent COULTER® LH Series Pak COULTER® LH Series RETIC Pak COULTER® Lyse S® III lytic agent COULTER® Lyse S® 4 lytic agent	COULTER® DH Diluent COULTER® DH Diff Pack COULTER® DH Retic Pack COULTER® DH Cell Lyse

Characteristic	COULTER® LH 750 (Predicate)	COULTER® LH 780 (Predicate)	UniCel® DxH 800
Cleaning Agent	COULTER® CLENZ	COULTER® LH Series Cleaner	COULTER® DH Cleaner

8.0 Summary of Performance Data:

Accuracy, repeatability (precision), measuring (linearity) range and carryover studies were conducted and demonstrated acceptable performance per the manufacturer specifications. The data in the Premarket Notification on safety and effectiveness supports a finding of substantial equivalence to products already in commercial distribution.

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
2098 Gaither Road
Rockville MD 20850

DEC 19 2008

Beckman Coulter, Inc.
C/o Lourdes Coba
11800 S.W. 147th Avenue
Miami, Florida 33196

Re: k081930
Trade/Device Name: Unicel® DxH 800® Coulter Cellular Analysis System
Regulation Number: 21 CFR 864.5220
Regulation Name: Automated Cell Counter
Regulatory Class: Class II
Product Code: GKZ
Dated: December 16, 2008
Received: December 17, 2008

Dear Ms. Coba:

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.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. 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); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820). This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed

predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of In Vitro Diagnostic Device Evaluation and Safety at 240-276-0450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. 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 (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

for Marian Chan, PhD
Acting Division Director
Division of Immunology and Hematology Devices
Office of In Vitro Diagnostic Device Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K081930

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

Indications For Use:

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:

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Prescription Use __X_ (21 CFR Part 801 Subpart D) And/Or Over The Counter Use ___ (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)

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

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