510(k) Summary
DxH™ 300 COULTER® Cellular Analysis System
DxH™ 300C COULTER® Cellular Analysis System

K106489
OCT 26 2010

1.0 **Submitted By:**

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2.0 **Date Submitted:**

February 18, 2010

3.0 **Device Name – Classification**

DxH™ 300 COULTER® Cellular Analysis System
DxH™ 300 COULTER® Cellular Analysis System
Automated differential cell counter
(21 CFR § 864.5220)

4.0 **Predicate Devices:**

Candidate	Predicate	Manufacturer	Docket Number
DxH™ 300 and DxH™ 300C COULTER® Cellular Analysis System	COULTER ® AcT Diff 2™ COULTER® LH 780 Hematology Analyzer	Beckman Coulter, Inc.	K990352 K061616

5.0 **Description:**

DxH™ 300 and DxH™ 300C COULTER® Cellular Analysis Analyzers are intended for In Vitro Diagnostic Use in clinical laboratories. The DxH 300C has the capability to process samples in an open and close vial mode of operation; the DxH 300 only operates in an open vial mode. The DxH 300 Systems provide automated complete blood count and leukocyte differentials.

The purpose of the DxH 300 Systems are 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, platelet distribution and manual White Blood Cell (WBC) differential as supplemental diagnostic results.

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 and colorimetric method. Additional reagents provide system cleaning and quality control and calibration. The system determines the parameters listed below along with the display of Red Blood Cell (RBC), Platelet and 3-part differential histograms.
Parameters : WBC, Lymph #, Mo #, Gran#, Lymph %, Mo%, Gran%, RBC, HGB, HCT%, MCV, MCH, MCHC, RDW, RDW-SD, PLT, MPV.

It has two counting modes, whole blood and predilute mode. The difference in the two modes is the amount of sample aspirated and the amount of reagents added for the final dilution to be analyzed. The aspiration pathway and testing principle are the same.

6.0 **Intended Use:**

The DxH 300 COULTER Cellular Analysis System and the DxH 300C COULTER Cellular Analysis System are quantitative automated hematology analyzers for *in vitro* diagnostic use in clinical laboratories. The DxH 300 COULTER Cellular Analysis System and the DxH 300C COULTER Cellular Analysis System provide complete blood count, (WBC, RBC, HGB, HCT, MCV, MCH, MCHC, RDW, RDW-SD, PLT, MPV) and Leukocyte 3-Part Differential [LY (%/#), MO (%/#), GR (%/#)] for whole blood specimens, collected in a salt of EDTA [dipotassium (K2) or tripotassium (K3)] obtained by venipuncture, heel or fingerstick. The purpose of the DxH 300 and the DxH 300C is to identify normal human patients, with normal system-generated parameters, from patients whose results require additional studies.

7.0 **Comparison to Predicates:**

Attribute	**COULTER® AcT Diff 2 ™** Predicate for all Parameters except RDW-SD and extended Platelet/WBC Linearity	**COULTER® LH 780** Predicate for RDW-SD, Platelet and WBC extended Linearity	**DxH™ 300/300C COULTER® Cellular Analysis System**
Intended Use	The COULTER ACT Diff 2 analyzer is a quantitative, automated hematology analyzer and leukocyte differential counter For In Vitro Diagnostic Use in clinical laboratories. The purpose is to identify the normal human patient, with all normal system-generated parameters, and to flag or identify patient results that require additional studies.	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 DxH 300 COULTER Cellular Analysis System and the DxH 300C COULTER Cellular Analysis System are quantitative automated hematology analyzers for *in vitro* diagnostic use in clinical laboratories. The DxH 300 COULTER Cellular Analysis System and the DxH 300C COULTER Cellular Analysis System provide complete blood count, (WBC, RBC, HGB, HCT, MCV, MCH, MCHC, RDW, RDW-SD, PLT, MPV) and Leukocyte 3-Part Differential [LY (%/#), MO (%/#), GR (%/#)] for whole blood specimens, collected in a salt of EDTA [dipotassium (K2) or tripotassium (K3)] obtained by venipuncture, heel or fingerstick. The purpose of the DxH 300 and the DxH 300C is to identify normal human patients, with normal system-generated parameters, from patients whose results require additional studies.
Device Classification and Product Code	864.5220, Automated Cell Counter, GKZ	Same	Same
Parameters	WBC, RBC, Hgb, Hct, MCV, MCH, MCHC, RDW, Plt, MPV, LY%, MO%, GR%, LY#, MO# and GR#	WBC, RBC, Hgb, Hct, MCV, MCH, MCHC, RDW, RDW-SD, Plt, MPV, LY%, MO%, NE%, EO%, BA%, LY#, MO#, NE#, EO#, BA#, RBC%, NRBC#, RET%, RET#, IRF and MRV.	Same as AcT Diff 2 with the addition of RDW-SD
Quality Control Techniques	Daily Instruments Check, Commercial Controls, Patient Controls, Inter-laboratory Quality Assurance Program (IQAP)	Same as AcT Diff 2 PLUS Delta Checks, XB Analysis, Extended QC and XM Analysis	Same as AcT Diff 2 with addition of XB Analysis, Extended QC and XM Analysis

Attribute	**COULTER® AcT Diff 2 ™** Predicate for all Parameters except RDW-SD and extended Platelet/WBC Linearity	**COULTER® LH 780** Predicate for RDW-SD, Platelet and WBC extended Linearity	**DxH™ 300/300C COULTER® Cellular Analysis System**
Analysis Reagents	COULTER® ISOTON® III Diluent COULTER® LYSE S® III Diff 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	DxH™ 300 Pack-contains COULTER® DxH Diluent (Optimized Isoton 4 Diluent) and COULTER® DxH Cell Lyse (Same as Lyse S® 4 lytic agent) DxH 300 Rinse
Quality Control & Calibrators	COULTER® 4C® Plus Cell Control COULTER® 4C-ES Cell Control COULTER® S-CAL® Calibrator Kit COULTER® LIN-C® Linearity Control	COULTER® 5C® Cell Control COULTER® Latron™ Primer and Latron Control COULTER® LIN-C® Linearity Control COULTER® S-CAL® Calibrator Kit COULTER® Retic-C™ Cell Control	COULTER® 4C-EX 300 Cell Control COULTER® LIN-X Linearity Control COULTER® S-CAL® Calibrator Kit
Cleaning Agents	COULTER® AcT Rinse Shutdown Diluent	COULTER® LH Series Cleaner	COULTER® DxH Cleaner
Sample Introduction	Manual presentation for open or closed vial sampling whole blood analysis and pre-dilute mode	Manual presentation for open vial Automated presentation for closed vial sampling from 12 position cassette. Maximum load capacity 12 racks	Same as AcT Diff 2 except DxH 300 does not perform closed vial sampling

8.0 **Summary of Performance Data:**

DxH 300 and DxH 300C

Study	**Study Design**	**Study Results**
Accuracy	Based on CLSI EP9-A2, Method Comparison and Bias Estimation Using Patient Samples; Approved Guideline – Second Edition. Testing was done in accordance with CLSI H20-A2 Reference Leukocyte (WBC) Differential Count (Proportional) and Evaluation of Instrumental Methods; Approved Standard – Second Edition	The DxH 300 systems demonstrated comparable results to the predicate device with reagents stated above.

Study	Study Design	Study Results
Precision	Based on CLSI EP5-A2, Evaluation of Precision Performance of Quantitative Measurement Methods; Approved Guideline – Second Edition.	The DxH 300 systems demonstrated acceptable results with reagents stated above.
Linearity	Based on CLSI EP06-A, Evaluation of the Linearity of Quantitative Measurement Procedures: A Statistical Approach; Approved Guideline	The DxH 300 systems demonstrated acceptable linearity results.
Carryover	Reference to the ICSH document: 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	The DxH 300 systems demonstrated acceptable carryover results.
Specimens	Specimen collection was done in accordance with CLSI H3-A6- Procedures for the Collection of Diagnostic Blood Specimens by Venipuncture: Approved Standard- Sixth Edition	Acceptable sample and prepared sample stability results achieved.
Reference Values	Based on CLSI C28-A3, Defining, Establishing, and Verifying Reference Intervals in the Clinical Laboratory, Approved Guideline – Third Edition	Reference intervals established.
Performance	Testing was done in accordance with CLSI H20-A2 Reference Leukocyte (WBC) Differential Count (Proportional) and Evaluation of Instrumental Methods; Approved Standard – Second Edition	The DxH 300 systems analysis of normal and clinical samples met the internal validation acceptance criteria

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

Food and Drug Administration
10903 New Hampshire Avenue
Document Mail Center – WO66-0609
Silver Spring, MD 20993-0002

Beckman Coulter, Inc.
c/o Ms. Jeanne Roscoe
Senior Regulatory Specialist
11800 S.W. 147th Avenue MS 31 B06
Miami, FL 33196-2500

OCT 2 6 2010

Re: k100489
Trade/Device Name: DxH™ 300 and DxH™ 300C COULTER® Cellular Analysis Systems
Regulation Number: 21 CFR 864.5220
Regulation Name: Automated differential cell counter
Regulatory Class: Class II
Product Code: GKZ
Dated: September 29, 2010
Received: September 30, 2010

Dear Ms. Roscoe:

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 class II (Special Controls), 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); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); 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 Parts 801 and 809), please contact the Office of *In Vitro* Diagnostic Device Evaluation and Safety at (301) 796-5450. 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 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/cdrh/industry/support/index.html.

Sincerely yours,

Maria M Chan

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

Enclosure

Indication for Use

K100489

OCT 26 2010

510(k) Number (K100489):

Device Name: DxH™ 300 COULTER® Cellular Analysis Analyzer
DxH™ 300C COULTER® Cellular Analysis Analyzer

Indication For Use:

The DxH 300 COULTER Cellular Analysis System and the DxH 300C COULTER Cellular Analysis System are quantitative automated hematology analyzers for *in vitro* diagnostic use in clinical laboratories. The DxH 300 COULTER Cellular Analysis System and the DxH 300C COULTER Cellular Analysis System provide complete blood count, (WBC, RBC, HGB, HCT, MCV, MCH, MCHC, RDW, RDW-SD, PLT, MPV) and Leukocyte 3-Part Differential [LY (%/#), MO (%/#), GR (%/#)] for whole blood specimens, collected in a salt of EDTA [dipotassium (K2) or tripotassium (K3)] obtained by venipuncture, heel or fingerstick. The purpose of the DxH 300 and the DxH 300C is to identify normal human patients, with normal system-generated parameters, from patients whose results require additional studies.

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

510(k) K100489