510(k) Summary
COULTER® 4C®- EX 300 Cell Control

K100607

1. **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

NOV 18 2010

2. **Date Submitted:**

March 2, 2010

3. **Device Name(s):**

3.1 **Proprietary Names**

COULTER® 4C®-EX 300 Cell Control

3.2 **Classification Name**

Hematology quality control mixture
(21 CFR § 864.8625)

4. **Predicate Device:**

Candidate(s)	Predicate	Manufacturer	Docket Number
COULTER® 4C®-EX 300 Cell Control (with additional parameter, RDW-SD)	COULTER® 4C®-ES Cell Control	Beckman Coulter, Inc.	K010064

5. **Description:**

4C®-EX 300 Cell Control is a reference product prepared from treated, stabilized human erythrocytes in an isotonic medium. 4C®-EX 300 Cell Control also contains a stabilized, platelet-sized component, and fixed erythrocytes to simulate leukocytes. By design, 4C®-EX 300 Cell Control confirms and monitors instrument accuracy and precision performance by providing measurements for counting, sizing and hemoglobin determination.

6. **Intended Use:**

4C®-EX 300 Cell Control is a hematology quality control material used to monitor the performance of COULTER® hematology analyzers listed in the TABLE OF EXPECTED RESULTS in conjunction with specific COULTER reagents (Refer to your instrument specific instructions for use)

The assigned values and expected ranges on the TABLE OF EXPECTED RESULTS can be used to monitor instrument performance. This product can also be used to establish your own laboratory mean.

7. **Comparison to Predicate(s):**

COULTER® 4C®-EX 300 Cell Control with the additional parameter (RDW-SD) is identical to the current COULTER 4C®-ES Cell Control. RDW-SD is a derived parameter from the RBC histogram which is obtained on a new COULTER® hematology analyzer. The control product formulation and manufacturing processes were not modified to obtain the additional parameter.

8. **Summary of Performance Data:**

Study	Study Design	Study Results
Open and Closed Vial Stability	Evaluated open and closed vial stability of 3 lots of 4C®-EX 300 Cell Control over the shelf life of the product on a DxH 300 and DxH 300C.	4C®-EX 300 Cell Control demonstrated acceptable results.
Value Assignment Process	Value assignments for each lot of 4C®-EX 300 Cell Control are determined on validated systems using specific Beckman Coulter reagents. Assigned Values are confirmed by multiple analysis of the control product.	Established process for generating assigned value for 4C®-EX 300 Cell Control.
Range Determination Process	The expected ranges for RDW-SD were calculated by a bio-statistician based upon the assigned values and expected ranges of MCV and RDW parameters and the mathematical relationship between these parameters for each level of 4C®-EX 300 Cell Control.	Established RDW-SD expected ranges for each level of 4C®-EX 300 Cell Control.

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
Silver Spring, MD 20993-0002

Beckman Coulter, Inc.
c/o Ms. Lourdes Coba
Staff Regulatory Affairs Specialist
11800 SW 147 Avenue MS 31 B06
Miami, FL 33196

NOV 1 8 2010

Re: k100607
Trade/Device Name: COULTER 4C-EX 300 Cell Control
Regulation Number: 21 CFR 864.8625
Regulation Name: Hematology quality control mixture
Regulatory Class: Class II
Product Code: JPK
Dated: October 27, 2010
Received: October 28, 2010

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. 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 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, 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

NOV 18 2010

510(k) Number (if known): K100607

Device Name: COULTER® 4C®-EX 300 Cell Control

Indication For Use:

4C®-EX 300 Cell Control is a hematology quality control material used to monitor the performance of COULTER hematology analyzers listed in the TABLE OF EXPECTED RESULTS in conjunction with specific COULTER reagents (Refer to your instrument specific instructions for use).

The assigned values and expected ranges on the TABLE OF EXPECTED RESULTS can be used to monitor instrument performance. This product can also be used to establish your own laboratory mean.

Prescription Use ___X___ And/Or Over the Counter Use ____.
(21 CFR Part 801 Subpart D) (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) K100607