K030291

Summary of Safety & Effectiveness
COULTER® AcT™ 5diff Autoloader (AL)

APR 17 2003

1.0 **Submitted By:**

Lourdes Coba
Senior Regulatory Affairs Specialist
Beckman Coulter, Inc.
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Miami, Florida 33196-2500
Telephone: (305) 380-4079
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2.0 **Date Submitted:**

January 27, 2003

3.0 **Device Name(s):**

3.1 **Proprietary Names**

COULTER® AcT™ 5diff Autoloader (AL)

3.2 **Classification Name**

Automated Differential Cell Counter (21 CFR § 864.5220)

4.0 **Predicate Device:**

Candidate(s)	Predicate #1	Manufacturer	Docket Number
COULTER® AcT™ 5diff Autoloader (AL)	COULTER® HmX with Autoloader	Beckman Coulter, Inc.	K922704/A1
	Predicate #2	**Manufacturer**	**Docket Number**
	CELL-DYN® 4000*	Abbott Diagnostics**	K961439

* Trademark of Abbott Diagnostics
** Abbott Diagnostics, 5440 Patrick Henry Drive, Santa Clara, CA.

5.0 Description:

The COULTER® AcT™ 5diff Autoloader (AL) is a moderate cost 5-part differential hematology analyzer with autoloader and external computer workstation.

6.0 Intended Use:

The COULTER® AcT™ 5diff Autoloader (AL) hematology analyzer is a quantitative, automated hematology analyzer and leukocyte differential counter for in vitro diagnostic use in clinical laboratories.

Clinical Significance:

The purpose of the AcT 5diff AL is 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 or distribution, biochemical investigations, manual WBC differential or any other derivative test that helps diagnosis of the patient's condition.

7.0 Comparison to Predicate(s):

COULTER® AcT™ 5diff Autoloader (AL) is substantially equivalent to the Beckman Coulter HmX with Autoloader and the Abbott CELL-DYN 4000.

	Predicate Device (1) **Beckman Coulter HmX with Autoloader**	Predicate Device (2) **Abbott CELL-DYN CD4000**	Device **Beckman Coulter A^c•T 5diff AL**
Parameters	24 WBC, RBC, Hgb, Hct, MCV, MCH, MCHC, RDW, Plt, MPV, PDW*, Pct*, Lymphocyte % & #, Monocyte % & # Neutrophil % & # Eosinophil % & # Basophil % & # Reticulocyte % & # * These parameters are for Research Use Only (RUO). Not for use in diagnostic procedures	28 WBC, RBC, Hgb, Hct, MCV, MCH, MCHC, RDW, Plt, MPV, PDW*, Pct*, WBC Viable Fraction*, NRBC #, NRBC /100 WBC Lymphocyte % & #, Monocyte % & # Neutrophil % & # Eosinophil % & # Basophil % & # Reticulocyte % & # IRF * These parameters are for Research Use Only (RUO). Not for use in diagnostic procedures	26 WBC, RBC, Hgb, Hct, MCV, MCH, MCHC, RDW, Plt, MPV, PDW*, Pct*, Lymphocyte % & #, Monocyte % & # Neutrophil % & # Eosinophil % & # Basophil % & # Atypical Lymph % & #• Immature cell % & #• N/A • These parameters are for Research Use Only (RUO). Not for use in diagnostic procedures

Principles of Measurement			
WBC	Aperture impedance	Aperture Impedance / Laser Light Scatter-	Aperture impedance
RBC	Aperture impedance	Aperture Impedance / Laser Light Scatter	Aperture impedance
Hgb	Spectrophotometric	Spectrophotometric	Spectrophotometric
MCV	Aperture impedance	Aperture Impedance / Laser Light Scatter	Calculated from Hct
Hct	Calculated from MCV	Calculated from MCV	Aperture impedance
Plt	Aperture impedance	Aperture Impedance / Laser Light Scatter	Aperture impedance
Differential	Aperture impedance Conductivity, Laser Light Scatter (VCS)	Multi- angle Polarized Scatter Separation (MPASS)	Aperture Impedance Light Scattering
Retics	Laser Light Scatter	Laser Light Scatter	N/A
NRBC and Non viable cells	N/A	Laser Light Scatter	N/A
Sample Volume	Closed Vial Mode - 185µL Open Vial Mode- 125µL	Manual or Automatic Modes - 115µL	Open and Closed vial modes CBC profile - 30µL CBC/DIFF profile - 53µL
Throughput	Closed and Open Vial mode - 75 samples/hour Retics – 30 samples/hour	Closed tube mode – 115 samples/hour Open Tube mode – 72 samples/hour	Closed and Open vial mode – 80 samples/hour

8.0 Summary of Performance Data:

The data in the Premarket Notification on safety and effectiveness supports a finding of substantial equivalence studies of the COULTER® AcT 5diff AL Hematology Analyzer 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.

Administrative Information
COULTER® AcT™ 5diff Autoloader (AL)

1.0 SUBMITTED BY:

Beckman Coulter, Inc.
11800 SW 147th Avenue
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Miami, FL 33196-2500
Establishment Registration No. 1061932

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2.0 PRODUCT NAME:

A. PROPRIETARY NAME: COULTER® AcT™ 5diff Autoloader (AL)

B. CLASSIFICATION NAME: Automated Differential Cell Counter
(21 CFR § 864.5220)

3.0 CLASSIFICATION:

FDA classifies this instrument as a Class II device.

4.0 COMPLIANCE WITH § 514:

Neither performance standards nor other special controls have been promulgated for this test system.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

APR 17 2003

Ms. Lourdes Coba
Senior Regulatory Affairs Specialist
Beckman Coulter, Inc.
11800 S.W. 147 Avenue
M/S 31-Bo6
Miami, FL 33196-2500

Re: k030291
Trade/Device Name: COULTER® AcT™ 5diff Autoloader (AL) Hematology Analyzer
Regulation Number: 21 CFR 864.5220
Regulation Name: Automated Differential Cell Counter
Regulatory Class: Class II
Product Code: GKZ
Dated: January 27, 2003
Received: January 28, 2003

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 information about the application of labeling requirements to your device, or questions on the promotion and advertising of your device, please contact the Office of In Vitro Diagnostic Device Evaluation and Safety at (301) 594-3084. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html.

Sincerely yours,

Steven Gutman

Steven I. Gutman, M.D., M.B.A.
Director
Office of *In Vitro* Diagnostic Device
Evaluation and Safety
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K030291

Device Name: COULTER® AcT™ 5diff Autoloader (AL) Hematology Analyzer

Indications for Use:

The COULTER® AcT™ 5diff Autoloader (AL) hematology analyzer is a 26-parameter, fully automated hematology analyzer, including a five-part leukocyte differential counter, capable of analyzing samples in a closed-vial Autoloader mode or a Manual (Stat) mode (open- or closed-vial).

864.5240 Automated Differential Cell Counter

Identification. An automated differential cell counter is a device used to identify one or more of the formed elements of the blood. The device may also have the capability to flag, count, or classify immature or abnormal hematopoietic cells of the blood, bone marrow, or other body fluids. These devices may combine an electronic particle counting method, optical method, or a flow cytometric method utilizing monoclonal CD (cluster designation) markers. The device includes accessory CD markers.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-the-Counter Use _____
(per 21 CFR 801.109) Optional Format 1-2-96

Josephine Bautista

(Division Sign-Off)
Division of Clinical Laboratory Devices
510(k) Number K030291