OCT 1 2 2004

K042173

Summary of Safety & Effectiveness
COULTER® A^{C}•T™ 5diff Cap Pierce (CP)

1.0 **Submitted By:**

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2.0 **Date Submitted:**

August 10, 2004

3.0 **Device Name:**

3.1 **Proprietary Name**

COULTER® A^{C}•T™ 5diff Cap Pierce (CP)

3.2 **Classification Name**

Automated Differential Cell Counter (21 CFR § 864.5220)

The special control for this submission is the FDA document "Class II Special Controls Guidance Document: Premarket Notifications for Automated Differential Cell Counter for Immature or Abnormal Blood Cells; Final Guidance for Industry and FDA".

4.0 **Predicate Device(s):**

Candidate	Predicate #1	Manufacturer	Docket Number
COULTER® A^{C}•T™ 5diff Cap Pierce (CP)	COULTER® HmX with Autoloader	Beckman Coulter, Inc.	K922704/A1
	Predicate #2	**Manufacturer**	**Docket Number**
	COULTER® A^{C}•T™ 5diff Autoloader (AL)	Beckman Coulter, Inc.	K030291 K032013

5.0 Description:

The COULTER® A^c•T™ 5diff Cap Pierce (CP) is a moderate cost 5-part differential hematology analyzer that consists of the analyzer, a personal computer (PC) workstation and a printer.

6.0 Intended Use:

The COULTER® A^c•T™ 5diff Cap Pierce (CP) 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 or open vial mode.

Clinical Significance:

The purpose of the A^c•T™ 5diff CP 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, manual WBC differential or any other derivative test that helps diagnosis of the patient's condition.

7.0 Comparison to Predicate(s):

The COULTER® A^c•T™ 5diff Cap Pierce (CP) is substantially equivalent to the COULTER® HmX with Autoloader and the COULTER® A^c•T™ 5diff Autoloader (AL) from Beckman Coulter, Inc.

	Predicate Device (1)	**Predicate Device (2)**	**Device**
	Beckman Coulter HmX with AL	**Beckman Coulter A^c•T 5diff AL**	**Beckman Coulter A^c•T 5diff CP**
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	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	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	Aperture Impedance
RBC	Aperture Impedance	Aperture Impedance	Aperture Impedance
Hgb	Spectrophotometric	Spectrophotometric	Spectrophotometric
MCV	Aperture Impedance	Calculated from Hct	Calculated from Hct
Hct	Calculated from MCV	Aperture Impedance	Aperture Impedance
Plt	Aperture Impedance	Aperture Impedance	Aperture Impedance
Differential	Aperture Impedance Conductivity, Laser Light Scatter (VCS)	Aperture Impedance Light Scattering	Aperture Impedance Light Scattering
Retics	Laser Light Scatter	N/A	N/A
Sample Volume	Closed Vial Mode - 185µL Open Vial Mode- 125µL	Open and Closed Vial Modes CBC profile - 30µL CBC/DIFF profile - 53µL	Open and Closed Vial Modes CBC profile - 30µL CBC/DIFF profile - 53µL
Throughput	Closed and Open Vial Modes - 75 samples/hour Retics – 30 samples/hour	Closed and Open Vial Modes – Up to 80 samples/hour	Closed and Open Vial Modes – Up to 60 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® A^{c}•T™ 5diff Cap Pierce (CP) 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.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

Mr. Lourdes Coba
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OCT 1 2 2004

Re: k042173
Trade/Device Name: COULTER® A^c•T™ 5diff Cap Pierce (CP) Hematology Analyzer
Regulation Number: 21 CFR § 864.5220
Regulation Name: Automated differential cell counter
Regulatory Class: II
Product Code: GKZ
Dated: August 10, 2004
Received: August 11, 2004

Dear Mr. 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). 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) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html.

Sincerely yours,

Robert L. Becker, Jr., M.D., 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

510(k) Number (if known): K042173

Device Name: COULTER® A^c•T™ 5diff Cap Pierce (CP) Hematology Analyzer

Indications for Use:

The COULTER® A^c•T™ 5diff Cap Pierce (CP) 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 or open vial mode.

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

Division Sign-Off

Office of In Vitro Diagnostic Device Evaluation and Safety

510(k) K042173