K971469

h) **510(k) Summary** JUN 30 1997

COULTER® A^c·T TRON Cell Control

Date of Summary: April 16, 1997

Company/Institution name: Coulter Corporation,
11800 SW 147 Ave.
Miami, FL 33196, Mailcode 31-B06
Contact Name: Thomas J. English, Phone 1-305-380-4331

Common or usual name or classification name: Hematology Quality Control Mixture
Product name: COULTER® A^c·T TRON Cell Control
C.F.R. Section: 864.8625
Device Class: Class II

510(k) numbers of Coulter devices to which substantial equivalence is claimed:
COULTER® 4C® PLUS Cell Control, K964988

The product is a Hematology Quality Control Mixture which like the predicate device, COULTER® 4C® PLUS Cell Control, is used to monitor the performance of Coulter hematology analyzers. COULTER® A^c·T TRON Cell Control is prepared from stabilized erythrocytes and a red chromophore so that repeated measurements can be made to monitor daily performance of the instrument system. Assigned values are confirmed by multiple analyses of the control product.

Intended Use: COULTER® A^c·T TRON Cell Control is intended For In Vitro Diagnostic Use as a control to monitor the performance of the CBC parameters on the COULTER® A^c·T Series Systems. Instrument performance is monitored using the assigned ranges on the TABLE OF EXPECTED RESULTS and reagents designed by Coulter for these systems.

COULTER A^c·T TRON Cell Control has the same intended use as the predicate device. Both devices are used to monitor instrument performance. Both devices consist of stabilized erythrocytes and a platelet-sized component suspended in a bacteriostatic medium. Both have assigned values which are confirmed by multiple analyses of the control product.

The differences between COULTER A^c·T TRON cell control and COULTER 4C PLUS Cell Controls are: COULTER A^c·T TRON cell control utilizes a red chromophore measured spectrophotometrically to simulate hemoglobin. COULTER A^c·T TRON cell control monitors the volume of the lytic reagent but does not monitor the potency of the lytic reagent. The predicate device in the presence of lytic reagent forms a Met-Hgb complex which is measured spectrophotometrically. COULTER 4C PLUS Cell Control monitors both the volume and potency of the lytic reagent.

Nonclinical testing focused on performance characteristics of homogeneity and stability. Testing met all acceptance criteria for the following: precision tested by replicate measurements and stability tested by recovery of values within the Assigned Ranges (Table of Expected Results on the package insert).

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

Thomas J. English
Director, Regulatory Affairs
Coulter Corporation
P.O. Box 169015
Miami, Florida 33116-9015

JUN 30 1997

Re: K971469
COULTER® A^c.T Tron Cell Control
Regulatory Class: II
Product Code: JPK
Dated: April 18, 1997
Received: April 22, 1997

Dear Mr. English:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to 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). 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 (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the current Good Manufacturing Practice requirement, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic (QS) inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal Laws or Regulations.

Under the Clinical Laboratory Improvement Amendments of 1988 (CLIA-88), this device may require a CLIA complexity categorization. To determine if it does, you should contact the Centers for Disease Control and Prevention (CDC) at (770) 488-7655.

This letter will allow you to begin marketing your device as described in your 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 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4588. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsmamain.html".

Sincerely yours,

Steven Gutman

Steven I. Gutman, M.D., M.B.A.
Director
Division of Clinical
Laboratory Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

INDICATIONS FOR USE

510(k) **Number** (if known): N/A

Device Name: COULTER® A^c·T TRON Cell Control

Indications For Use:
COULTER® A^c·T TRON Cell Control is intended For In Vitro Diagnostic Use as a control to monitor the performance of the CBC parameters on COULTER® A^c·T Series Systems. Instrument performance is monitored using the assigned ranges on the TABLE OF EXPECTED RESULTS and reagents designed by Coulter for these systems.

(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 Form 1-2-96)

Patricia A. Bernhardt (for AWM) 6/26/97

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