

4/1/99

K990352

Summary of Safety & Effectiveness
COULTER® Ac-T diff 2™ Analyzer

1.0 Submitted By

Tom English
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Coulter Corporation
11800 SW 147 Avenue MC 31-B06
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2.0 Date Submitted

January 27, 1999

3.0 Device Name(s)

3.1 Proprietary Names

COULTER® Ac-T diff 2™ Analyzer

3.2 Classification Names

An automated differential cell counter is a device used to identify and classify one or more of the formed elements of blood. (CFR 864.5220)

4.0 Predicate Device(s)

COULTER® Ac-T diff™ Analyzer (K973634)
COULTER® COUNTER® S-PLUS IV and LYSE S PLUS D (K823355)

5.0 Description

The COULTER® Ac-T diff 2™ Analyzer is a quantitative, automated hematology analyzer and leukocyte differential counter For In Vitro Diagnostic Use in clinical laboratories. COULTER® Ac-T diff 2™ Analyzer has the same technological characteristics and is substantially equivalent to the COULTER® COUNTER® S-PLUS IV and LYSE S PLUS D (also called COULTER COUNTER® Model S PLUS IV with Three Population Differential and Model S PLUS IV Diff), which was cleared by 510(k) K823355 on Dec. 28, 1982 and is a modified version of the COULTER® Ac-T diff™ Analyzer which were cleared by 510(k) K973634 on October 29, 1997.

As with the predicate devices, the COULTER® Ac-T diff 2™ Analyzer utilizes the Coulter principle for the enumeration and sizing of blood cells, in combination with an automatic diluting and mixing device for sample processing and a single beam photometer for the measurement of hemoglobin. The same reagent system, composed of an isotonic diluent, lytic reagent to lyse red blood cells for WBC and hemoglobin measurement and instrument cleaner, is used on Model S PLUS IV Diff and Ac-T diff Analyzers.

All the devices determine the following CBC parameters:

WBC	(Leukocyte count)
	LY # (Lymphocyte number)
	LY% (Lymphocyte percent)
	MO # (Mononuclear number)
	MO % (Mononuclear percent)
	GR # (Granulocyte number)
	GR % (Granulocyte percent)
RBC	(Erythrocyte count)
Hgb	(Hemoglobin)
Hct	(Hematocrit)
MCV	(Mean Corpuscular Volume)
MCH	(Mean Corpuscular Hemoglobin)
MCHC	(Mean Corpuscular Hemoglobin Concentration)
Plt	(Platelet or thrombocyte count)
RDW	(Red Cell Distribution Width)
MPV	Mean Platelet (thrombocyte) Volume
Pct*	Plateletcrit
PDW*	Platelet Distribution Width

*These parameters are not for diagnostic use but can be used as internal instrument checks on the platelet parameters.

Like the Ac-T diff Analyzer, the Ac-T diff 2 can analyze samples in either of two modes: whole blood and pre-dilute. Additionally, the Ac-T diff 2 can sample closed vial specimens by virtue of a rotary cap piercing functionality. The MODEL S PLUS IV Diff does not have a pre-dilute mode or a closed vial sampling mode.

6.0 **Intended Use:**

The COULTER® Ac-T diff 2 analyzer is a quantitative, automated hematology analyzer and leukocyte differential counter intended For In Vitro Diagnostic Use in clinical laboratories.

7.0 **Comparison to Predicate(s):**

The following tables outline the basic similarities and differences between the Ac-T diff 2 analyzer and the predicate devices.

SIMILARITIES to the PREDICATES

COULTER® A ^C ·T diff 2™ Analyzer	COULTER®A ^C ·T diff™ Analyzer	COULTER® S-PLUS IV with Diff
Utilizes the Coulter principle for enumeration and sizing of blood cells.	Utilizes the Coulter principle for enumeration and sizing of blood cells.	Utilizes the Coulter principle for enumeration and sizing of blood cells.
Utilizes an automatic sampling, diluting and mixing device for sample processing.	Utilizes an automatic sampling, diluting and mixing device for sample processing.	Utilizes an automatic sampling, diluting and mixing device for sample processing.
Reagent system includes isotonic diluent, lytic reagent and cleaning agent.	Reagent system includes isotonic diluent, lytic reagent and cleaning agent.	Reagent system includes isotonic diluent, lytic reagent and cleaning agent.
Simultaneous analysis of RBC and WBC in separate analysis vessels.	Simultaneous analysis of RBC and WBC in separate analysis vessels.	Simultaneous analysis of RBC and WBC in separate analysis vessels.
Utilizes sweep flow to prevent cells from re-entering the sensing zone and being counted as platelets.	Utilizes sweep flow to prevent cells from re-entering the sensing zone and being counted as platelets.	Utilizes sweep flow to prevent cells from re-entering the sensing zone and being counted as platelets.
Ability to set normal patient ranges against which sample results are compared. Sample results are flagged with "H" if the result is above the normal range and "L" if below the normal range.	Ability to set normal patient ranges against which sample results are compared. Sample results are flagged with "H" if the result is above the normal range and "L" if below the normal range.	Ability to set normal patient ranges against which sample results are compared. Sample results are flagged with "H" if the result is above the normal range and "L" if below the normal range.
Uses a single aperture each for WBC and RBC counting and sizing.	Uses a single aperture each for WBC and RBC counting and sizing.	Uses three apertures each for WBC and RBC counting and sizing.
Parameters: WBC, RBC, Hgb, Hct, MCV, MCH, MCHC, Plt, LY % & LY #, MO% & MO #, GR % & GR #, RDW, MPV. Pct and PDW are also measured but not intended for diagnostic use.	Parameters: WBC, RBC, Hgb, Hct, MCV, MCH, MCHC, Plt, LY % & LY #, MO% & MO #, GR % & GR #, RDW, MPV. Pct and PDW are also measured but not intended for diagnostic use.	Parameters: WBC, RBC, Hgb, Hct, MCV, MCH, MCHC, Plt, LY % & LY #, MO% & MO #, GR % & GR #, RDW, MPV. Pct and PDW are also measured but not intended for diagnostic use.
Instrument calculates a three-population leukocyte count (LY %, MO%, GR %) from the WBC histogram based on cell size. Cells between 35 fL and 90 fL are classified as lymphocytes. The absolute number for each population is then compared	Instrument calculates a three-population leukocyte count (LY %, MO%, GR %) from the WBC histogram based on cell size. Cells between 35 fL and 90 fL are classified as lymphocytes. The absolute number for each population is then compared	Instrument calculates a three-population leukocyte count (LY %, MO%, GR %) from the WBC histogram based on cell size. Cells between 35 fL and 90 fL are classified as lymphocytes. The absolute number for each population is then compared
Ability to store data.	Ability to store data.	Ability to store data.
Automated Calibration and Control calculations.	Automated Calibration and Control calculations.	Automated Calibration and Control calculations.
Automated, self-cleaning probe.	Automated, self-cleaning probe.	See DIFFERENCES table
Uses Universal Icons for operator interface.	Uses Universal Icons for operator interface.	See DIFFERENCES table.



APR 1 1999

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Mr. Tom English
Manager, Premarket Product
Regulatory Compliance
Coulter Corporation
11800 SW 147 Avenue MC 31-B06
Miami, Florida 33196

Re: K990352
Trade Name: COULTER® Ac-T diff 2™ Analyzer
Regulatory Class: II
Product Code: GKZ
Dated: January 27, 1999
Received: February 5, 1999

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 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). 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 requirements, 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.

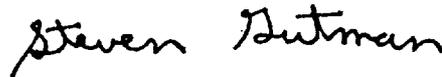
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Under the Clinical Laboratory Improvement Amendments of 1988 (CLIA-88), this device may require a CLIA complexity categorization. To determine if it does, you should contact the Centers for Disease Control and Prevention (CDC) at (770) 488-7655.

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/dsma/dsmamain.html>".

Sincerely yours,

A handwritten signature in black ink that reads "Steven Gutman". The signature is written in a cursive style with a large initial 'S' and 'G'.

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 STATEMENT

510(k) Number (if known): K 990352
~~TO BE ASSIGNED~~

Device Name: COULTER® AC-T diff 2™ Analyzer

Indications For Use:

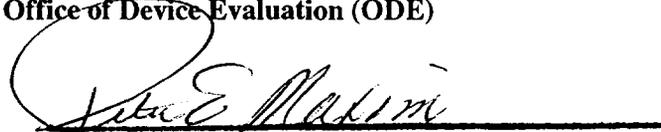
The COULTER® AC-T diff 2™ analyzer is a quantitative, automated hematology analyzer and leukocyte differential counter For In Vitro Diagnostic Use in clinical laboratories.

21 CFR 864.5220 Automated differential cell counter

An automated differential cell counter is a device used to identify and classify one or more of the formed elements of blood.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)



(Division Sign-Off)

Division of Clinical Laboratory Devices

510(k) Number

K 990352

Prescription Use
(Per 21 CFR 801.109)

OR

Over-The-Counter Use

(Optional Form 1-2-96)