

K993356

Summary of Safety & Effectiveness
COULTER® Hematology Analyzers with IRF & MRV Parameters

1.0 **Submitted By**

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APR 20 2000

2.0 **Date Submitted**

March 28, 2000

3.0 **Device Name(s)**

3.1 **Proprietary Names**

COULTER® Hematology Analyzers with IRF & MRV Parameters

3.2 **Classification Names**

The product is classified as a Class III device as found in 21CFR 864.5220.

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) .The Classification Number is 81GKZ.

4.0 **Predicate Device(s)**

Sysmex™ w/IRF Parameter (K971736/S1), COULTER® GEN-S™ System (K962988), COULTER® New Methylene Blue Prep Retic MAXM/AL Analyzers (K925344)

5.0 **Description**

The Immature Reticulocyte Fraction expresses the number of early reticulocytes as a proportion of the total reticulocyte count. Mean reticulocyte volume (MRV) is the average cell volume of the reticulocytes, determined by the VCS Technology algorithm and is reported in femtoliters (fL). This 510(k) Premarket Notification provides information demonstrating that Coulter hematology analyzers with IRF and MRV parameters are substantially equivalent to products previously cleared for this use. The COULTER hematology analyzers with IRF and MRV parameters are compared to Sysmex™ hematology analyzers with the IRF parameter. The MRV parameter is presented as a discussion of the calculation and supported by precision data from a COULTER GEN-S System analyzer. Unlike the Sysmex R-1000, R-3000 and RAM-1 analyzers which are dedicated to the measurement of reticulocyte parameters, the COULTER hematology analyzers, including the GEN-S, measure multiple CBC and differential parameters in addition to the measurement of reticulocyte parameters.

6.0 **Intended Use**

The COULTER hematology analyzers with IRF and MRV parameters are quantitative, automated hematology analyzers and leukocyte differential counters intended For In Vitro Diagnostic Use in clinical laboratories. These systems also provide automated Reticulocyte analysis.

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

The following table show the basic similarities and differences between the COULTER® GEN-S and predicate device(s).

SIMILARITIES TO THE PREDICATE

COULTER hematology analyzers with IRF and MRV parameters	Sysmex SE & R Series
Systems provide automated reticulocyte analysis	Same
Report IRF parameter	Same*

*Reported as sum of MFR (Middle Fluorescence Ratio) and HFR (High Fluorescence Ratio)

DIFFERENCES FROM THE PREDICATE:

COULTER hematology analyzers with IRF and MRV parameters	Sysmex R Series
Quantitative, automated hematology analyzers and leukocyte differential counters	Measures reticulocyte parameters only
Report MRV parameters	No MRV analysis
Measure CBC, 5-part differential and reticulocyte parameters	Measures reticulocyte parameters only
Use impedance for counting and sizing RBCs and platelets	No RBC or platelet analysis
Reticulocyte parameters derived from laser light scatter and nucleic acid dye (New Methylene Blue)	Reticulocyte parameters are measured by fluorescence and light scatter utilizing a fluorescent dye (Auramine-O)

8.0 Summary of Performance Data:

The data in the Premarket Notification on safety and effectiveness supports a finding of substantial equivalence to hematology analyzers already in commercial distribution. Equivalence is demonstrated through compared sample accuracy and imprecision experiments.

IRF Accuracy Analysis : GEN•S vs Sysmex SE9500

PARAMETER	IRF
UNITS	Not Applicable
POPULATION MEAN Predicate Method	0.199
POPULATION MEAN Comparator Method	0.391
MEAN DIFFERENCE	-0.192
SD OF DIFFERENCE	0.07953
SLOPE	0.835
Y-INTERCEPT	0.225
R	0.757
N	332

IRF and MRV Paired Imprecision results: GEN•S

	IRF	MRV
Units	Not Applicable	Femtoliters (fL)
N	90	90
Population Minimum	0.127	93.6
Population Maximum	0.372	123.2
Mean difference	0	0.04
S.D. of Difference	0.04	2.33

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

APR 20 2000

Stan Sugrue, Ph.D.
Senior Regulatory Affairs Specialist
Coulter Corporation
11800 SW 147 Avenue MC 31-B06
Miami, Florida 33196

Re: K993356
Trade Name: COULTER® Hematology Analyzers with IRF & MRV Parameters
Regulatory Class: III
Product Code: GKZ
Dated: March 28, 2000
Received: March 29, 2000

Dear Dr. Sugrue:

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.

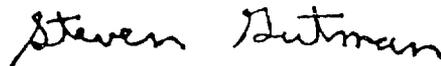
If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially 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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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" (21CFR 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, prominent "S" at the beginning.

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): 993356

Device: COULTER Hematology Analyzers with IRF and MRV Parameters

Indications For Use:

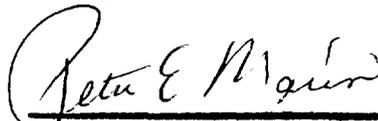
The COULTER GEN-S System with IRF and MRV Parameters is a quantitative, automated hematology analyzer and leukocyte differential counter For In Vitro Diagnostic Use in clinical laboratories. The COULTER GEN-S System also provides automated Reticulocyte analysis.

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.

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NEEDED) _____

Concurrence of CDRH, Office of Device Evaluation (ODE)



(Division Sign-Off)

Division of Clinical Laboratory Devices

510(k) Number

993356

Prescription Use
(Per 21 CFR 801.109)

OR

Over-The-Counter Use

(Optional Form 1-2-96)