

MAY 11 1999

K991070

Summary of Safety and Effectiveness
COULTER® Z2 Analyzer

1.0 Submitted By:

Tom English
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2.0 Date Submitted:

March 30, 1999

3.0 Device Names:

3.1 Proprietary Name(s):

COULTER® Z2 Analyzer

3.2. Classification Name(s):

Automated cell counter (21 CFR §864.5200)

4.0 Predicate Device(s):

COULTER® Z1 Analyzer
COULTER® STKS Analyzer

5.0 Description

COULTER Z2 has the same technological characteristics and is substantially equivalent to the COULTER® STKS analyzer that was cleared by 510(k) K885093 cleared on Dec. 28, 1988.

The COULTER Z2 is the same device as the COULTER® Z1, cleared by 510(k) K952308 on October 6, 1995 except for the measurement of two additional parameters, Mean Cell Volume (MCV) and Mean Platelet Volume (MPV) and the ability to provide the operator with on-screen/printed graphs of channelized size distribution data.

The COULTER Z2 is a general purpose dual threshold particle counter and sizer designed to count and size particles, suspended in an aqueous electrolyte solution, within the range of 1 to 120 μm equivalent spherical diameter. The instrument is designed for both biological and industrial use.

As with the predicate devices, the COULTER Z2 utilizes the Coulter principle for the enumeration and sizing of blood cells. The same reagent system, composed of an isotonic diluent, lytic reagent to lyse red blood cells for WBC measurement and instrument cleaner, is used on COULTER STKS, Z1, and Z2 instruments.

The COULTER STKS, Z1, and Z2 instruments are capable of determining the human erythrocyte concentration (Red Cell Count or RBC), leukocyte concentration (White Cell Count or WBC) and thrombocyte concentration (Platelet Count or Plt). In addition, like the COULTER STKS, the COULTER Z2 also provides the mean erythrocyte volume (Mean Cell Volume or MCV) and the mean thrombocyte volume (Mean Platelet Volume or MPV).

Both the COULTER Z1 and the Z2 instruments contain a hydraulic metering station built into the electronics main unit, measure a restricted range of particle

sizes (within the range 1 to 120 μM) and utilize surface-mount technology. Operator-adjustable controls are accessible by means of a keyboard data terminal.

6.0. Intended use:

The COULTER® Z Series Analyzers is a semi-automated device that may be used for in vitro diagnostic use to determine the human erythrocyte concentration (Red Cell Count or RBC), leukocyte concentration (White Cell Count or WBC) and thrombocyte concentration (Platelet Count or Plt). In addition, the COULTER Z2 also provides the mean erythrocyte volume (Mean Cell Volume or MCV) and the mean thrombocyte volume (Mean Platelet Volume or MPV).

This submission provides information concerning the safety and effectiveness principally of the two parameters added to the instrument.

7.0 Comparison to Predicate(s):

The following tables outline the basic similarities and differences between the Z2 and the predicate devices.

SIMILARITIES to the PREDICATES

COULTER® Z2	COULTER® Z1	COULTER® STKS
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.
Reagent system includes an isotonic diluent, lytic reagent and instrument cleaner.	Reagent system includes an isotonic diluent, lytic reagent and instrument cleaner.	Reagent system includes an isotonic diluent, lytic reagent and instrument cleaner.
Ability to print sample results.	Ability to print sample results.	Ability to print sample results.
Uses coincidence correction. The frequency of coincidence is a statistically predictable function of particle concentration and is corrected by the instrument.	Uses coincidence correction. The frequency of coincidence is a statistically predictable function of particle concentration and is corrected by the instrument.	Uses coincidence correction. The frequency of coincidence is a statistically predictable function of particle concentration and is corrected by the instrument.
The ability to provide the operator with on-screen/printed graphs of channelized size distribution data.	See DIFFERENCES table	The ability to provide the operator with on-screen/printed graphs of channelized size distribution data.
Separate measurement of RBC, WBC and PLT is required.	Separate measurement of RBC, WBC and PLT is required.	See DIFFERENCES table
Uses a single aperture each for WBC and RBC counting and sizing.	Uses a single aperture each for WBC and RBC counting and sizing.	See DIFFERENCES table
No ability to store data.	No ability to store data.	See DIFFERENCES table
Automated Calibration calculation but operator intervention required for Control calculations.	Automated Calibration calculation but operator intervention required for Control calculations.	See DIFFERENCES table
Sample probe requires manually cleaning	Sample probe requires manually cleaning	See DIFFERENCES table
Uses detachable keypad for operator interface.	Uses detachable keypad for operator interface.	See DIFFERENCES table.
System does not measure hemoglobin	System does not measure hemoglobin	See DIFFERENCES table
Requires external dilutor to supply the proper volume of diluent for predilute samples.	Requires external dilutor to supply the proper volume of diluent for predilute samples.	See DIFFERENCES table

DIFFERENCES from the PREDICATES

COULTER® Z2	COULTER® Z1	COULTER® STKS
Can be used For In Vitro Diagnostic Use for Red Blood Cell Count (RBC), White Blood Cell Count (RBC), Platelet (Plt), Mean Cell Volume (MCV), Mean Platelet Volume (MPV).	Can be used For In Vitro Diagnostic Use for Red Blood Cell Count (RBC), White Blood Cell Count(WBC), Platelet (Plt),. Does <u>not</u> measure Mean Cell Volume (MCV), Mean Platelet Volume.	Can be used For In Vitro Diagnostic Use for Red Blood Cell Count (RBC), White Blood Cell Count (WBC), Platelet (Plt), Mean Cell Volume (MCV), Mean Platelet Volume (MPV). Other parameters include a five-part leukocyte differential count, hemoglobin, hematocrit, mean cell hemoglobin, mean cell hemoglobin concentration and red cell distribution width.
The ability to provide the operator with on-screen/printed graphs of channelized size distribution data.	No channelizing capability	See SIMILARITIES table
Manual dilution of blood samples.	See SIMILARITIES table	Automated diluton of blood samples.
Uses a single aperture each for WBC and RBC counting and sizing.	See SIMILARITIES table	Uses three apertures each for WBC and RBC counting and sizing.
System does not measure hemoglobin	See SIMILARITIES table	The system uses the lysed WBC dilution to measure Hgb in the WBC bath. A beam of incandescent light passes through the WBC bath and then through a 525-nm optical filter and is measured by a photodiode.
No ability to store data.	See SIMILARITIES table	Ability to store data.
Requires external dilutor to supply the proper volume of diluent for predilute samples.	See SIMILARITIES table	Ability to dispense the proper volume of diluent for predilute samples.
Automated Calibration calculation but operator intervention required for Control calculations.	See SIMILARITIES table	Automated Calibration and Control calculations.
Uses detachable keypad for operator interface.	See SIMILARITIES table	Uses Universal Icons for operator interface.
Sample probe requires manually cleaning	See SIMILARITIES table	Automated, self-cleaning probe.
Separate measurement of RBC, WBC and PLT is required.	See SIMILARITIES table	Simultaneous measurement of all parameters.

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 results.

COULTER Z2 Analyzer Imprecision Analysis by Reproducibility

PARAMETER	UNITS	MEAN	SD	CV%
RBC	X 10 ⁶ cells/ μ L	4.77	.0981	2.06
PLT	x 10 ³ cells/ μ L	153.8	4.54	2.95
MPV	fL	7.99	0.12	1.48
MCV	fL	83.14	0.73	0.87

COULTER Z2 Analyzer ACCURACY ANALYSIS: COMPARED SAMPLES

PARAMETER	UNITS	N	POP. MIN	POP. MAX	MEAN DIFF.	SD	MEAN % DIFF	CORR COEFF
RBC	x 10 ⁶ cells/ μ L	31	3.50	6.02	0.16	0.24	3.51	0.90
MCV	fL	31	78.0 0	97.46	0.54	2.7	0.65	0.82
PLT	x 10 ³ cells/ μ L	31	134	483	56.23	50.09	23.13	0.82
MPV	FL	31	7.15	11.27	0.55	0.43	6.52	0.89



DEPARTMENT OF HEALTH & HUMAN SERVICES

MAY 11 1999

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

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

Re: K991070
Trade Name: COULTER® Z2 Analyzer
Regulatory Class: II
Product Code: GKL
Dated: March 30, 1999
Received: March 31, 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.

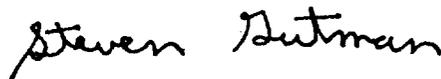
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Under the Clinical Laboratory Improvement Amendments of 1988 (CLIA-88), this device may require a CLIA complexity categorization. To determine if it does, you should contact the Centers for Disease Control and Prevention (CDC) at (770) 488-7655.

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.

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

INTENDED USE STATEMENT

510(k) Number (if known): K 991070
~~TO BE ASSIGNED~~

Device Name: COULTER® Z2 Analyzer

Intended Use:

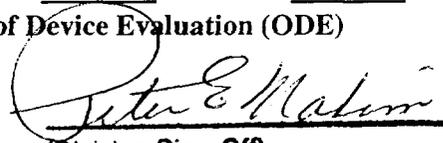
The COULTER® Z2 instrument may be used for *in vitro diagnostic* use to determine the human erythrocyte concentration (Red Cell Count or RBC), leukocyte concentration (White Cell Count or WBC) and thrombocyte concentration (Platelet Count or Plt). In addition, the COULTER Z2 also provides the mean erythrocyte volume (Mean Cell Volume or MCV) and the mean thrombocyte volume (Mean Platelet Volume or MPV).

21 CFR 864.5200 Automated cell counter

An automated cell counter is a fully-automated or semi-automated device used to count red blood cells, white blood cells, or blood platelets using a sample of the patients peripheral blood (blood circulating in one of the body's extremities, such as the arm). These devices may also measure hemoglobin or hematocrit and may also calculate or measure one or more of the red cell indices (the erythrocyte mean corpuscular volume, the mean corpuscular hemoglobin, or the mean corpuscular hemoglobin concentration). These devices may use either an electronic particle counting method or an optical counting method.

(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 K991070

Prescription Use
(Per 21 CFR 801.109)

OR

Over-The-Counter Use

(Optional Form 1-2-96)