K061616

BECKMAN COULTER

510(k) Summary
COULTER® LH 780 Hematology Analyzer

OCT - 4 2006

1.0 Submitted By:

Nancy Nadler
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2.0 Date Submitted:

June 8, 2006

3.0 Device Name(s):

3.1 Proprietary Names

COULTER® LH 780 Hematology Analyzer

3.2 Classification Name

Automated differential cell counter
(21 CFR § 864.5220)

4.0 Predicate Devices:

Candidate	Predicates	Manufacturer	Docket Number
COULTER® LH 780 Hematology Analyzer	COULTER® LH 750 Hematology Analyzer	Beckman Coulter, Inc.	K011342
	COULTER® LH 750 Body Fluids Application (for Body Fluids equivalence only)	Beckman Coulter, Inc.	K030606
	Sysmex™ Automated Hematology Analyzer XE-2100 (for RDW SD Parameter equivalence only)	Sysmex Corporation	K992875

5.0 Description:

The COULTER LH 780 Hematology Analyzer is designed For In Vitro Diagnostic Use in clinical laboratories. The LH 780 provides automated complete blood count, leukocyte differential, NRBC enumeration and reticulocyte analysis as well as an automated method for enumeration of RBCs and WBCs in body fluids

The purpose of the LH 780 Hematology Analyzer 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 platelet distribution, manual WBC differential or any other definitive test that helps diagnose the patient's condition.

The instrument system is comprised of the analyzer and a suite of analytical reagents that allow for simultaneous quantitative determination of hemoglobin measurement, cell counting and sizing, reticulocyte determination, quality control, calibration and cleaning.

6.0 Intended Use:

The COULTER LH 780 Hematology Analyzer is a quantitative, automated hematology analyzer and leukocyte differential counter For In Vitro Diagnostic Use in clinical laboratories. The COULTER LH 780 Hematology Analyzer provides automated Reticulocyte analysis and enumeration of nucleated red blood cells (NRBCs) as well as an automated method for enumeration of RBCs and WBCs in body fluids.

7.0 Comparison to Predicate(s):

Characteristic	COULTER LH 750 (Predicate)	COULTER LH780
Intended Use	The COULTER LH 750 Hematology Analyzer is a quantitative, automated hematology analyzer and leukocyte differential counter For In Vitro Diagnostic Use in clinical laboratories. The COULTER LH 750 Hematology Analyzer provides automated Reticulocyte analysis and enumeration of nucleated red blood cells (NRBCs) as well as an automated method for enumeration of RBCs and WBCs in body fluids.	Same as LH 750 except referring to the LH 780
Parameters IVD	WBC, RBC, Hgb, Hct, MCV, MCH, MCHC, RDW, Plt, MPV, LY%, MO%, NE%, EO%, BA%, LY#, MO#, NE#, EO#, BA#, NRBC%, NRBC#, RET%, RET#, IRF, & MRV.	Same as LH 750 plus RDW-SD
Quality Control Techniques	Daily Instruments Check, Commercial Controls, Delta Checks, Patient Controls, XB Analysis, & IQAP.	Same as LH 750 plus Extended QC & XM Analysis
Quality Controls & Calibrator	COULTER® 5C® Cell Control COULTER® Latron™ Primer and Latron Control COULTER® RETIC-C™ Cell Control COULTER® LIN-C® linearity control COULTER® S-CAL® calibrator kit	Same as LH 750

Characteristic	COULTER LH 750 (Predicate)	COULTER LH 780
Analysis Reagents	COULTER® LH Series Diluent COULTER® Isoton 4 Diluent COULTER® LH Series Pak COULTER® LH Series RETIC Pak COULTER® Lyse S® III lytic agent COULTER® Lyse S® 4 lytic agent	Same as LH 750
Cleaning Agent	COULTER® CLENZ	Same as LH 750 plus COULTER® LH Series Cleaner
New Features (not covered above)	n/a	• RBC correction • Graphical representation of customer-definable high / low limits on the RBC histogram • Advanced bar-code reader • Control folder filters • Reproducibility and carryover not required as pre-calibration checks

8.0 Summary of Performance Data:

Accuracy, precision, linearity and carryover studies were conducted and demonstrated acceptable performance per the manufacturer specifications. The data in the Premarket Notification on safety and effectiveness supports a finding of substantial equivalence 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.

3. Device Comparison Table

Characteristic	COULTER LH 750 (Predicate)	COULTER LH 780
Intended Use	The COULTER LH 750 Hematology Analyzer is a quantitative, automated hematology analyzer and leukocyte differential counter For In Vitro Diagnostic Use in clinical laboratories. The COULTER LH 750 Hematology Analyzer provides automated Reticulocyte analysis and enumeration of nucleated red blood cells (NRBCs) as well as an automated method for enumeration of RBCs and WBCs in body fluids.	Same as LH 750 except referring to the LH 780
Indication For Use	The purpose of the LH 700 Series 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 platelet distribution, manual WBC differential or any other definitive test that helps diagnose the patient's condition.	Same as LH 750
Parameters IVD	WBC, RBC, Hgb, Hct, MCV, MCH, MCHC, RDW, Plt, MPV, LY%, MO%, NE%, EO%, BA%, LY#, MO#, NE#, EO#, BA#, NRBC%, NRBC#, RET%, RET#, IRF, & MRV.	Same as LH 750 plus RDW-SD
Quality Control Techniques	Daily Instruments Check, Commercial Controls, Delta Checks, Patient Controls, XB Analysis, & IQAP.	Same as LH 750 plus Extended QC & XM Analysis
Method History	Coulter Principle, Hemoglobinometry, VCS technology, & NRBC enumeration.	Same as LH 750
Quality Controls & Calibrator	COULTER® 5C® Cell Control COULTER® Latron™ Primer and Latron Control COULTER® RETIC-C™ Cell Control COULTER® LIN-C® linearity control COULTER® S-CAL® calibrator kit	Same as LH 750
Analysis Reagents	COULTER® LH Series Diluent COULTER® Isoton 4 Diluent COULTER® LH Series Pak COULTER® LH Series RETIC Pak COULTER® Lyse S® III lytic agent COULTER® Lyse S® 4 lytic agent	Same as LH 750
Cleaning Agent	COULTER® CLENZ	Same as LH 750 plus COULTER® LH Series Cleaner
Performance Specifications	Within-Run precision (CBC, Diff, Retic), Accuracy(CBC, Diff, Retic), Linearity (WBC, RBC, Hgb, & Plt), Background (WBC, RBC, Hgb, & Plt), Operating and Reportable Ranges (CBC, Diff, Retic, NRBC), & Mode to Mode Comparison (WBC, RBC, Hgb, Plt).	Same as LH750 plus Within-Run precision, Accuracy, and Operating and Reportable Ranges include RDW-SD and a tighter WBC Linearity specification
Service diagnostics	Uses ProService Remote Diagnostics	Same as LH 750
Hardware Options	Graphic/Laser Printer, LH 700 Series SlideMaker, & LH 700 Series SlideStainer.	Same as LH 750
Uncorrected WBC (UWBC)	Result reported in a comment field	Result reported in parameter block

TABLE 1: COULTER® LH 780 Hematology Analyzer Whole Blood Parameters (con't):

NE%	Neutrophil percent
EO%	Eosinophil percent
BA%	Basophil percent
LY#	Lymphocyte number
MO#	Monocyte number
NE#	Neutrophil number
EO#	Eosinophil number
BA#	Basophil number
NRBC%	Nucleated Red Blood Cell percent
NRBC#	Nucleated Red Blood Cell number
RET%	Reticulocyte percent
RET#	Reticulocyte number
IRF	Immature Reticulocyte Fraction
MRV	Mean Reticulocyte Volume

Characteristic	COULTER LH 750 (Predicate)	COULTER LH 780
Parameters IVD	WBC, RBC, Hgb, Hct, MCV, MCH, MCHC, RDW, Plt, MPV, LY%, MO%, NE%, EO%, BA%, LY#, MO#, NE#, EO#, BA#, NRBC%, NRBC#, RET%, RET#, IRF, & MRV.	Same as LH 750 plus RDW-SD
Quality Control Techniques	Daily Instruments Check, Commercial Controls, Delta Checks, Patient Controls, XB Analysis, & IQAP.	Same as LH 750 plus Extended QC & XM Analysis
Method History	Coulter Principle, Hemoglobinometry, VCS technology, & NRBC enumeration.	Same as LH 750
Quality Controls & Calibrator	COULTER® 5C® Cell Control COULTER® Latron™ Primer and Latron Control COULTER® RETIC-C™ Cell Control COULTER® LIN-C® linearity control COULTER® S-CAL® calibrator kit	Same as LH 750
Analysis Reagents	COULTER® LH Series Diluent COULTER® Isoton 4 Diluent COULTER® LH Series Pak COULTER® LH Series RETIC Pak COULTER® Lyse S® III lytic agent COULTER® Lyse S® 4 lytic agent	Same as LH 750
Cleaning Agent	COULTER® CLENZ	Same as LH 750 plus COULTER® LH Series Cleaner
Performance Specifications	Within-Run precision (CBC, Diff, Retic), Accuracy(CBC, Diff, Retic), Linearity (WBC, RBC, Hgb, & Plt), Background (WBC, RBC, Hgb, & Plt), Operating and Reportable Ranges (CBC, Diff, Retic, NRBC), & Mode to Mode Comparison (WBC, RBC, Hgb, Plt).	Same as LH750 plus Within-Run precision, Accuracy, and Operating and Reportable Ranges include RDW-SD and a tighter WBC Linearity specification
Service diagnostics	Uses ProService Remote Diagnostics	Same as LH 750
Hardware Options	Graphic/Laser Printer, LH 700 Series SlideMaker, & LH 700 Series SlideStainer.	Same as LH 750
Uncorrected WBC (UWBC)	Result reported in a comment field	Result reported in parameter block
New Features (not covered above)	n/a	• RBC correction • Graphical representation of customer-definable high / low limits on the RBC histogram • Advanced bar-code reader • Control folder filters • Reproducibility and carryover not required as pre-calibration checks

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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OCT - 4 2006

Re: k061616
Trade/Device Name: COULTER® LH 780 Hematology Analyzer
Regulation Number: 21 CFR § 864.5220
Regulation Name: Automated differential cell counter
Regulatory Class: II
Product Code: GKZ
Dated: September 20, 2006
Received: September 21, 2006

Dear Ms. Nadler:

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 (240) 276-0484. 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/industry/support/index.html

Sincerely yours,

Robert L. Becker, Jr., MD, Ph.D
Director
Division of Immunology and Hematology
Office of *In Vitro* Diagnostic Device
Evaluation and Safety
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K061616

Device Name: **COULTER® LH 780 Hematology Analyzer**

Indications For Use: The COULTER LH 780 Hematology Analyzer is a quantitative, automated hematology analyzer and leukocyte differential counter For In Vitro Diagnostic Use in clinical laboratories. The COULTER LH 780 Hematology Analyzer provides automated Reticulocyte analysis and enumeration of nucleated red blood cells (NRBCs) as well as an automated method for enumeration of RBCs and WBCs in body fluids.

Prescription Use __X_ AND/OR Over-The-Counter Use ___
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

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

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

Division Sign-Off

Office of In Vitro Diagnostic Device Evaluation and Safety

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