JUL 2 9 2002

K022161

Section 1 D: Summary of Safety and Effectiveness for COULTER® LH 750 Hematology Analyzer with Version 2A Software

1.0 General Information

Device Generic Name(s):	Automated differential cell counter
Device Trade Name(s):	COULTER® LH 750 Hematology Analyzer
Device Classification:	The COULTER® LH 750 Hematology Analyzer is a Class II medical device.
Applicant Name and Address:	Beckman Coulter, Inc. Cellular Analysis Division 11800 SW 147 Avenue Miami, FL 33196-2500
Date:	July 2, 2002

2.0 Legally Marketed Device(s)

The modified COULTER® LH 750 Hematology Analyzer with Version 2A Software claims substantial equivalence to the previously cleared COULTER® LH 750 Hematology Analyzer with Version 1A software.

FDA 510(k) Number(s): K011342

3.0 Device Description

The product is an automated hematology analyzer capable of supplying a complete blood cell analysis and includes a differential leukocyte cell count. The product also provides automated reticulocyte analysis and enumeration of nucleated red blood cells (NRBCs). The following reagents, with 510(k) numbers indicated where applicable, are qualified for use on the COULTER LH 750 Hematology Analyzer with Version 2A software:

- 5C® -ES Cell Control (K010066) and COULTER RETIC-C™ Cell control (K930119) hematology quality control materials used to monitor the instrument performance. COULTER® LIN-C® linearity control (K955334) verifies reportable range of the CBC parameters.
- COULTER® LH 700 SERIES Diluent. Intended for use as a diluent for counting and sizing blood cells on COULTER® LH 700 SERIES hematology analyzers.
- COULTER Lyse S® III diff. Intended for the simultaneous quantitative determination of hemoglobin and for leukocyte counting and sizing on COULTER® hematology analyzers.
- COULTER CLENZ® cleaning agent to prevent protein buildup on surfaces.

- COULTER Latron™ Primer and Latron Control (K885028) to monitor VCS performance.

- COULTER LH 700 SERIES Pak, containing Erythrolyse™ lytic reagent and Stabilyse™ to preserve leukocytes in near-native state to allow differentiation into subpopulations.

- COULTER LH 700 SERIES RETIC Pak, containing Reagent A and Reagent B, is used for clearing red cells and staining reticulocytes.

- COULTER S-CAL® Hematology Calibrator (K840794), alternative to whole blood reference method of calibration. Intended for use in ensuring accurate instrument measurements.

4.0 Principle of Method:

The COULTER LH 750 Hematology Analyzer with Version 2A software has the same technological characteristics and is substantially equivalent to the COULTER LH 750 Hematology Analyzer with Version 1A software. Both devices utilize the Coulter Principle for enumerating and sizing blood cells, automatic diluting and mixing for sample processing and a single beam photometer for hemoglobinometry. They use COULTER VCS (volume, conductivity, light scatter) technology for WBC Differential analysis and classification and reticulocyte analysis. The analyzers use a reagent system consisting of an isotonic diluent, lytic reagents to lyse the red cells without significantly affecting the white cells and an instrument cleaner. Additionally, all systems include reagents used for reticulocyte staining and analysis.

5.0 Indications for 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 also provides automated reticulocyte analysis and nucleated red blood cell (NRBC) enumeration.

6.0 Description of the modification:

The currently marketed COULTER LH 750 hematology analyzer with Version 1A software release was modified with software and minor hardware changes to improve performance characteristics and reliability.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

JUL 2 9 2002

Stan Sugrue, Ph.D.
Senior Regulatory Affairs Specialist
Premarket Product Regulatory Compliance
Beckman Coulter Inc.
11800 SW 147 Avenue
MC 31-B06
Miami, FL 33196-2500

Re: k022161
Trade/Device Name: COULTER ® LH 750 Hematology Analyzer
Regulation Number: 21 CFR 864.5220
Regulation Name: Automated differential cell counter
Regulatory Class: Class II
Product Code: GKZ
Dated: July 2, 2002
Received: July 3, 2002

Dear Dr. Sugrue:

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 the Code of Federal Regulations, Title 21, Parts 800 to 898. 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 Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

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 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/dsma/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

Section 1C: INDICATIONS FOR USE

510(k) Number (if known): ~~Not assigned~~ K022161

Device: COULTER® LH 750 Hematology Analyzer

Indications For 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 also provides automated Reticulocyte analysis and enumeration of nucleated red blood cells (NRBCs).

Future commercialization will add ISOTON® 4 diluent /Lyse S® 4 Lytic reagent to the indications for use.

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)

Prescription Use ✓ **OR** **Over-The-Counter Use** _____
(Per 21 CFR 801.109)

Josephine Bautista
(Division Sign-Off)
Division of Clinical Laboratory Devices
510(k) Number K022161