K052905

NOV 1 8 2005

## Section 1 D: Summary of Safety and Effectiveness for COULTER® LH 750 Hematology Analyzer

### 1.0 General Information

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|---|---|
| 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.<br>Cellular Analysis Division<br>11800 SW 147 Avenue<br>Miami, FL 33196-2500 |
| Date: | October 13, 2005 |

### 2.0 Legally Marketed Device(s)

The modified COULTER® LH 750 Hematology Analyzer claims substantial equivalence to the previously cleared COULTER® LH 750 Hematology Analyzer.

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, enumeration of nucleated red blood cells (NRBCs) in whole blood and leukocytes (WBC) and erythrocytes (RBC) in cerebrospinal fluid, serous fluids, and synovial fluid. The following reagents, with 510(k) numbers indicated where applicable, are qualified for use on the COULTER LH 750 Hematology Analyzer with Version 2B (or higher) software:

- 5C® Cell Control (K781969) 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 or ISOTON 4 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 or Lyse S® 4. 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 Analyzers utilizes 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.

For body fluids analysis, specimen is aspirated into the LH 700 Series Analyzer via the manual mode and is diluted in separate WBC and RBC baths. The Coulter Method of counting cells is used to detect and measure changes in electrical resistance when a cell, suspended in a conductive diluent, passes through a small aperture. Each suspended cell acts as an insulator. As the cell passes through the aperture, it momentarily increases the resistance of the electrical path between two submerged electrodes, one located on each side of the aperture. The resistance generates an electrical pulse. The accumulation of electrical pulses are channelized, processed for coincidence correction, and multiplied by a calibration factor, yielding the WBC and RBC counts.

The WBC result represents the TNC (total nucleated cell count) in the analysis of Body Fluids.

## 5.0 Indications for Use (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.

## 6.0 Description of the modification:

The labeling for the marketed COULTER LH 750 hematology analyzer will be modified relative to draft product labeling submitted in the original premarket notification (K011342) to reflect new instructions for performing QC for NRBC determinations.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

NOV 1 8 2005

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

Re: k052905
Trade/Device Name: COULTER® LH 750 Hematology Analyzer: Change to NRBC QC Method
Regulation Number: 21 CFR § 864.5220
Regulation Name: Automated differential cell counter
Regulatory Class: II
Product Code: GKZ
Dated: October 13, 2005
Received: October 14, 2005

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 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

## Section 1C: INDICATIONS FOR USE

K052905

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

**Device:** COULTER® LH 750 Hematology Analyzer

**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.

**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.

**Prescription Use** X **OR** **Over-The-Counter Use** ___

**(Per 21 CFR 801.109)**

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

**Concurrence of CDRH, Office of Device Evaluation (ODE)**

Robert A Becker J

Division Sign-Off

Office of In Vitro Diagnostic Device Evaluation and Safety

510(k) K052905