OCT 2 9 2004

K042724

Section 1 D: Summary of Safety and Effectiveness for COULTER® LH 500 Hematology Analyzer with Version 2A Software

1.0 General Information

Device Generic Name(s):	Automated differential cell counter
Device Trade Name(s):	COULTER® LH 500 Hematology Analyzer
Device Classification:	The COULTER® LH 500 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:	September 30, 2004

2.0 Legally Marketed Device(s)

The modified COULTER® LH 500 Hematology Analyzer with Version 2A Software claims substantial equivalence to the previously cleared COULTER® LH 500 Hematology Analyzer with Version 1A software.

FDA 510(k) Number(s): K032000

3.0 Device Description

LH 500 hematology analyzer is designed For In Vitro Diagnostic Use in clinical laboratories. The LH 500 provides automated complete blood count and leukocyte differential and semi-automated reticulocyte analysis. The purpose of the LH 500 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.

4.0 Principle of Method:

CBC (Complete Blood Count) Analysis (Whole Blood)
CBC analysis is based on the established Coulter principle method of automated cell counting and spectrophotometric hemoglobin determination. The Coulter method counts and sizes cells by detecting and measuring changes in electrical resistance when a particle (such as a cell) in a conductive liquid goes through a small aperture.

Each cell suspended in a conductive liquid (diluent) acts as an insulator. As each cell goes through the aperture, it momentarily increases the resistance of the electrical path between two submerged electrodes, one located on each side of the aperture. This causes an electrical pulse that can be counted and sized. While the number of pulses indicates particle count, the size of the electrical pulse is proportional to the cell volume.

Differential and Reticulocyte Analysis (Whole Blood)

Differential and reticulocyte Analysis is based on the Coulter volume, conductivity and light scatter technology (VCS). Differential analysis and classification and reticulocyte analysis occur in the flow cell, where:

Low-frequency current measures volume,

High-frequency current senses cellular internal content through measuring changes in conductivity,

Light from the laser scattered off the individual cells characterizes cellular surface, shape and reflectivity.

5.0 Indications for Use:

The COULTER® LH 500 is a quantitative, automated hematology analyzer For In Vitro Diagnostic Use in clinical laboratories. The LH 500 System provides automated complete blood count and leukocyte differential. The product also provides semi- automated reticulocyte analysis.

6.0 Description of the modification:

The currently marketed COULTER LH 500 hematology analyzer with Version 1A software release was modified with software algorithm changes to allow use of cyanide-free reagents (ISOTON 4 diluent /LYSE S 4 lytic agent). Additional software modifications were made to mitigate observed anomalies of earlier versions and various corrections, clarifications and minor performance testing results were added to operator labeling.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

OCT 2 9 2004

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

Re: k042724
Trade/Device Name: COULTER® LH 500 Hematology Analyzer with Version 2A Software
Regulation Number: 21 CFR § 864.5220
Regulation Name: Automated differential cell counter
Regulatory Class: II
Product Code: GKZ, GKL
Dated: October 18, 2004
Received: October 19, 2004

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 (301) 594-3084. 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/dsma/dsmamain.html.

Sincerely yours,

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

Enclosure

Section 1C: INDICATIONS FOR USE

510(k) Number (if known): K042724

Device: COULTER® LH 500 Hematology Analyzer

Intended use:

The COULTER® LH 500 is a quantitative, automated hematology analyzer For In Vitro Diagnostic Use in clinical laboratories. The LH 500 System provides automated complete blood count and leukocyte differential. The product also provides semi- 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.

(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)

Division Sign-Off

Office of In Vitro Diagnostic Device Evaluation and Safety

510(k) K042724