AUG 1 3 2003

K032000

Section 1 D: 510(k) Summary of Safety and Effectiveness for LH 500 hematology analyzer

1.0 General Information

Applicant Name and Address:	Beckman Coulter, Inc. Cellular Analysis Division 11800 SW 147 Avenue Miami, FL 33196-2500
Primary Contact:	Stan Sugrue, Ph.D. Senior Regulatory Affairs Specialist Telephone: (305) 380-4552 FAX: (305) 380-3618 E-mail: stan.sugrue@coulter.com
Date:	June 26, 2003
Device Trade Name(s):	LH 500 hematology analyzer
Device Generic Name(s):	Automated differential cell counter
Device Classification:	The LH 500 hematology analyzer is a Class II medical device.

2.0 Predicate Device

The LH 500 hematology analyzer claims substantial equivalence to COULTER LH 750 hematology analyzer.

FDA 510(k) Number(s): K011342

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.

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.

4.0 Principle of Method:

The COULTER LH 500 Hematology Analyzer has the similar technological characteristics and is substantially equivalent to the COULTER LH 750 Hematology Analyzer. 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 Comparison to Predicate

Comparison	Characteristic	COULTER LH 750 (Predicate)	COULTER LH 500
Similarities	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.	Same as LH 750
	Analysis Reagents	COULTER® LH Series Diluent COULTER LH SERIES Pak COULTER Lyse S® III diff lytic agent	Same as LH 750
	Cleaning Agent	COULTER CLENZ	Same as LH 750
	Hematology Quality Controls	COULTER® 5C Cell Control COULTER® Latron Primer and Latron Control RETIC-C Cell Control Lin-C linearity control	Same as LH 750
Differences	Reticulocyte analysis method	Automated	Semi automated
	Reticulocyte analysis reagent system	LH SERIES RETIC Pak	COULTER ReticPrep Reagent Kit
	Aperture system	Utilizes a triple aperture configuration	Utilizes a single aperture configuration

6.0 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 and semi-automated reticulocyte analysis.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

AUG 13 2003

Stan Sugrue, Ph.D.
Senior Regulatory Affairs Specialist
Beckman Coulter, Inc.
Cellular Analysis Division
11800 SW 147 Avenue
Miami, Florida 33196-2500

Re: k032000
Trade/Device Name: Coulter® LH 500 Hematology Analyzer
Regulation Number: 21 CFR § 864.5220
Regulation Name: Automated differential cell counter
Regulatory Class: II
Product Code: GKZ
Dated: June 26, 2003
Received: June 27, 2003

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,

Steven Gutman

Steven I. Gutman, M.D., M.B.A.
Director
Office of In Vitro Diagnostic Device Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

Section 1C: INDICATIONS FOR USE

[redacted]

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

Device: COULTER® LH 500

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.

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)

Division Sign-Off

Office of In Vitro Diagnostic Device Evaluation and Safety

510(k) K032000