JUN 1 1 2002

K021150

Summary of Safety & Effectiveness
COULTER® CellPrep

1.0 **Submitted By:**

Lourdes Coba
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2.0 **Date Submitted:**

April 9, 2002

3.0 **Device Name(s):**

3.1 **Proprietary Names**

COULTER® CellPrep

3.2 **Classification Name**

Automated blood cell diluting apparatus (21 CFR § 864.5240)

4.0 **Predicate Device:**

Candidate(s)	Predicate	Manufacturer	Docket Number
COULTER® CellPrep	COULTER® Multi-Q-Prep	Beckman Coulter, Inc.	K923530

5.0 **Description:**

The COULTER® CellPrep is a compact, fully automated sample processing workstation which can be programmed to perform a variety of cell wash, dilution, and concentration operations.

6.0 Intended Use:

The COULTER® CellPrep is an automated system that processes human blood for preparation of leukocyte suspensions for quantitative immunofluorescence analysis by optical flow cytometers.

The use of data generated by this instrument depends on the regulatory status of the reagents you use. If the reagent is labeled by the manufacturer "For Research Use Only. Not for use in diagnostic procedures," federal law prohibits the use of the data for diagnosis.

This product is intended "For In Vitro Diagnostic Use" when using the "IVDImmunophenotype" protocol and processing whole blood samples with COULTER reagents and antibodies labeled for In Vitro Diagnostic Use.

Clinical Significance:
Separation of cells with a phenotypic low antigen density from cells with no phenotypic specificity can be modulated by a simple removal of background fluorescence such as plasma, media, excess tagged antibody, and fluorescent drug compounds. Removal of these components increases the fluorescent separation of positive and negative cells.

7.0 Comparison to Predicate(s):

COULTER® CellPrep is similar to the COULTER® Multi-Q-Prep.

8.0 Summary of Performance Data:

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.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

JUN 11 2002

Mr. Lourdes Coba
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Beckman Coulter, Inc.
11800 S.W. 147 Avenue
M/S 31-B06
Miami, Florida 33196-2500

Re: k021150
Trade/Device Name: COULTER® CellPrep
Regulation Number: 21 CFR § 864.5240
Regulation Name: Automated blood cell diluting apparatus
Regulatory Class: I
Product Code: GKH
Dated: April 9, 2002
Received: April 10, 2002

Dear Mr. Coba:

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

510(k) Number (if known):

Device Name: COULTER® CellPrep

Indications for Use:

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The use of data generated by this instrument depends on the regulatory status of the reagents you use. If the reagent is labeled by the manufacturer "For Research Use Only. Not for use in diagnostic procedures," federal law prohibits the use of the data for diagnosis.

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864.5240 Automated blood cell diluting apparatus

Identification. An automated blood cell diluting apparatus is a fully automated or semi-automated device used to make appropriate dilutions of a blood sample for further testing.

(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) Optional Format 1-2-96

Josephine Gautista

(Division Sign-Off)
Division of Clinical Laboratory Devices
510(k) Number K021150