K030408

MAR 0 4 2003

Section 1 D: Summary of Safety and Effectiveness for CYTO-STAT® tetraCHROME™ CD45-FITC/CD4-PE/CD8-ECD/CD3-PC5 and CYTO-STAT® tetraCHROME™ CD45-FITC/CD56-PE/CD19-ECD/CD3-PC5 Monoclonal Antibody Reagents

1.0 General Information

Device Generic Name(s):	Lymphocyte Immunophenotyping monoclonal antibody reagents
Device Trade Name(s):	CYTO-STAT® tetraCHROME™ CD45-FITC/CD4-PE/CD8-ECD/CD3-PC5 and CYTO-STAT® tetraCHROME™ CD45-FITC/CD56-PE/CD19-ECD/CD3-PC5 Monoclonal Antibody Reagents
Device Classification:	CYTO-STAT® tetraCHROME™ CD45-FITC/CD4-PE/CD8-ECD/CD3-PC5 and CYTO-STAT® tetraCHROME™ CD45-FITC/CD56-PE/CD19-ECD/CD3-PC5 Monoclonal Antibody Reagents are Class II medical devices.
Applicant Name and Address:	Beckman Coulter, Inc. Cellular Analysis Division 11800 SW 147 Avenue Miami, FL 33196-2500
Date:	February 6, 2003

2.0 Legally Marketed Device(s)

The CYTO-STAT® tetraCHROME™ CD45-FITC/CD4-PE/CD8-ECD/CD3-PC5 and CYTO-STAT® tetraCHROME™ CD45-FITC/CD56-PE/CD19-ECD/CD3-PC5 Monoclonal Antibody Reagents claims substantial equivalence to the previously cleared tetraONE System for EPICS XL Flow Cytometry System with CYTO-STAT® tetraCHROME™ CD45-FITC/CD4-PE/CD8-ECD/CD3-PC5 Monoclonal Antibody Reagent and with CYTO-STAT® tetraCHROME™ CD45-FITC/CD56-PE/CD19-ECD/CD3-PC5 Monoclonal Antibody Reagent

FDA 510(k) Number(s): K990172

3.0 Device Description

The products are:

The CYTO-STAT® tetraCHROME™ CD45-FITC/CD4-PE/CD8-ECD/CD3-PC5 Monoclonal Antibody Reagent and CYTO-STAT® tetraCHROME™ CD45-FITC/CD56-PE/CD19-ECD/CD3-PC5 Monoclonal Antibody Reagent. Each is a combination of four murine monoclonal antibodies, each conjugated to a different fluorochrome and specific for a different cell surface antigen. Specifically,

- CYTO-STAT tetraCHROME CD45-FITC/CD4-PE/CD8-ECD/CD3-PC5 Monoclonal antibody reagent allows the identification and enumeration of Total CD3+ (T cells), Total CD4+, Total CD8+, Dual CD3+/CD4+, Dual CD3+/CD8+ lymphocyte percentages and absolute counts as well as the CD4/CD8 ratio in whole

blood flow cytometry. When used in conjunction with CD45-FITC/CD56-PE/CD19-ECD/CD3-PC5, the total lymphocyte percentage can be obtained.

- CD45-FITC/CD56-PE/CD19-ECD/CD3-PC5 Monoclonal antibody reagent allows the identification and enumeration of total CD19+ (B cells) and CD3-/CD56+ (NK cells) lymphocyte percentages and absolute counts in whole blood flow cytometry. The total lymphocyte percentage can be obtained as well.

4.0 Principle of Method:

The CYTO-STAT® tetraCHROME™ CD45-FITC/CD4-PE/CD8-ECD/CD3-PC5 and CYTO-STAT® tetraCHROME™ CD45-FITC/CD56-PE/CD19-ECD/CD3-PC5 Monoclonal Antibody Reagents are combinations of four murine monoclonal antibodies, each conjugated to a different fluorochrome and specific for a different cell surface antigen. The test depends on the ability of a monoclonal antibody to bind to the surface of cells expressing discrete antigenic determinants. Red blood cell are lysed and the remaining white blood cells are analyzed on a flow cytometer (COULTER EPICS XL, FC 500 or equivalent flow cytometer). The analysis may be automated, as with XL with System II software which automates standardization of light scatter, fluorescence intensities and adjustment of color compensation settings and tetraONE SYSTEM software which provides automated analysis of lymphocyte subpopulations. Alternatively, the operator may perform the analysis by adjusting gating and other operational parameters to optimize results when working with non-routine samples.

5.0 Indications for Use:

CYTO-STAT tetraCHROME CD45-FITC/CD4-PE/CD8-ECD/CD3-PC5 Monoclonal antibody reagent is intended "For In Vitro Diagnostic Use", allowing the identification and enumeration of Total CD3+ (T cells), Total CD4+, Total CD8+, Dual CD3+/CD4+, Dual CD3+/CD8+ lymphocyte percentages and absolute counts as well as the CD4/CD8 ratio in whole blood flow cytometry. When used in conjunction with CD45-FITC/CD56-PE/CD19-ECD/CD3-PC5, the total lymphocyte percentage can be obtained. CD45-FITC/CD56-PE/CD19-ECD/CD3-PC5 monoclonal antibody reagent is intended "For In Vitro Diagnostic Use", allowing the identification and enumeration of total CD19+ (B cells) and CD3-/CD56+ (NK cells) lymphocyte percentages and absolute counts in whole blood flow cytometry. The total lymphocyte percentage can be obtained as well.

6.0 Description of the modification:

The currently marketed tetraONE System for EPICS XL Flow Cytometry System with CYTO-STAT® tetraCHROME™ CD45-FITC/CD4-PE/CD8-ECD/CD3-PC5 Monoclonal Antibody Reagent and with CYTO-STAT® tetraCHROME™ CD45-FITC/CD56-PE/CD19-ECD/CD3-PC5 Monoclonal Antibody Reagent is an automated analysis method for simultaneous identification and enumeration of lymphocyte subpopulations (CD3+, CD4+, CD8+, CD19+and CD56+) combining four-color fluorescent monoclonal antibody reagents, quality control reagents, optional absolute count reagent and software. This premarket notification is for the use of the two monoclonal antibody reagent system components as stand alone reagents on any equivalent flow cytometer system, allowing the operator to manually adjust gating and other operational parameters to optimize results at their discretion.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
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Rockville MD 20850

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Senior Regulatory Affairs Specialist
Premarket Product Regulatory Compliance
Beckman Coulter, Inc.
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MAR 0 4 2003

Re: k030408
Trade/Device Name: CYTO-STAT® tetraCHROME™ CD45-FITC/CD4-PE/CD8-ECD/CD3-PC5 and CYTO-STAT® tetraCHROME™ CD45-FITC/CD56-PE/CD19-ECD/CD3-PC5 Monoclonal Antibody Reagents
Regulation Number: 21 CFR § 864.5220
Regulation Name: Lymphocyte Immunophenotyping monoclonal antibody reagents
Regulatory Class: II
Product Code: GKZ
Dated: February 6, 2003
Received: February 7, 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

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

Device: CYTO-STAT® tetraCHROME™ CD45-FITC/CD4-PE/CD8-ECD/CD3-PC5 and CYTO-STAT® tetraCHROME™ CD45-FITC/CD56-PE/CD19-ECD/CD3-PC5 Monoclonal Antibody Reagents

Indications For Use:

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CD45-FITC/CD56-PE/CD19-ECD/CD3-PC5 Monoclonal antibody reagent is intended "For In Vitro Diagnostic Use", allowing the identification and enumeration of total CD19+ (B cells) and CD3-/CD56+ (NK cells) lymphocyte percentages and absolute counts in whole blood flow cytometry. This reagent can also provide the total lymphocyte percentage.

21 CFR 864.5220

Lymphocyte Immunophenotyping monoclonal antibody reagents

(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)
Division of Clinical Laboratory Devices
510(k) Number K030408