MAY 21 2003

K030828

Section 1 D: 510(k) Summary of Safety and Effectiveness for tetraCXP SYSTEM for the Cytomics FC 500 with CXP Software

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:	March 13, 2003
Device Trade Name(s):	tetraCXP SYSTEM for the Cytomics FC 500 with CXP Software
Device Generic Name(s):	Automated differential cell counter
Device Classification:	The tetraCXP SYSTEM for the Cytomics FC 500 with CXP Software is a Class II medical device.

2.0 Predicate Device

The tetraCXP SYSTEM for the Cytomics FC 500 with CXP Software claims substantial equivalence to the tetraONE SYSTEM for EPICS XL Flow Cytometry SYSTEM with CYTO-STAT tetraCHROME CD45-FITC/CD4-RD1/CD8-ECD/CD3-PC5 Monoclonal Antibody Reagent and CYTO-STAT tetraCHROME CD-45-FITC/CD56-RD1/CD19-ECD/CD3-PC5 Monoclonal Antibody Reagent.

FDA 510(k) Number(s): K990172

3.0 Device Description

tetraCXP SYSTEM for the Cytomics FC 500 with CXP Software consists of CYTO-STAT tetraCHROME CD45-FITC/CD4-RD1/CD8-ECD/CD3-PC5 and CYTO-STAT tetraCHROME CD-45-FITC/CD56-RD1/CD19-ECD/CD3-PC5 monoclonal antibody reagents, quality control reagents, an optional absolute count reagent, and automated application and operating software on the Cytomics FC 500 Flow Cytometer.

4.0 Principle of Method:

This test depends upon the ability of an monoclonal antibody to bind to the surface of cells expressing discrete antigenic determinants. Specific cell staining is accomplished by incubating whole blood with monoclonal antibody reagent. Red blood cells are lysed and the remaining white cells are analyzed on the FC 500 flow cytometry systems with CXP software and the tetraCXP SYSTEM (reagent application) software packages. The tetraCXP SYSTEM reagent application software, in conjunction with CXP operating system software on the FC 500 flow cytometer, tetraCHROME monoclonal antibody reagents, provides automated analysis of lymphocyte subpopulations.

5.0 Comparison to Predicate

Comparison	Characteristic	tetraONE System (Predicate)	tetraCXP System
Similarities	Intended Use	Enumeration of total T, B, and NK lymphocytes and three major lymphocyte subset populations	Same as tetraONE
	Analysis Reagents	CYTO-STAT® tetraCHROME™ CD45-FITC/CD4-RD1/CD8-ECD/CD3-PC5 CYTO-STAT® tetraCHROME™ CD45-FITC/CD56-RD1/CD19-ECD/CD3-PC5 Flow-Count™ Fluorospheres	Same as tetraONE
	AutoSetup Reagents	Flow-Set™ Fluorospheres CYTO-COMP™ Cell Kit	Same as tetraONE
	QC Reagents	CYTO-TROL™ Control Cells or IMMUNO-TROL™ Cells IMMUNO-TROL™ Low Cells	Same as tetraONE
	Automated Analysis Algorithm	cellSTAT 3D™ algorithm	Based on cellSTAT 3D™ algorithm
Differences	Flow Cytometer	EPICS® XL-MCL™ flow cytometry system	CYTOMICS FC 500 flow cytometry system
	System Software	System II	CXP
	AutoSetup Reagents	CYTO-COMP™ Reagent Kit	QuickCOMP 4 Kit

6.0 Indications for Use:

The tetraCXP SYSTEM for the Cytomics FC 500 flow cytometry systems 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 CXP software. The system with 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. The system 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.

7.0 Conclusion:

The tetraCXP SYSTEM for the Cytomics FC 500 flow cytometry systems is substantially equivalent 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 CYTO-STAT® tetraCHROME™ CD45-FITC/CD56-PE/CD19-ECD/CD3-PC5 Monoclonal Antibody Reagent.

Section 1 F: **ADMINISTRATIVE INFORMATION**

1.0 Submitted By

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

Secondary Contact:
Deborah Herrera
Group Manager, Regulatory Affairs
Telephone: (305) 380-4013
FAX: (305) 380-3618
E-mail: debbie.herrera@coulter.com

2.0 Sponsor Address/FDA Registration Number

Beckman Coulter, Inc.
Cytomics Division
11800 SW 147 Avenue
Miami, FL 33196-2500
FDA Establishment Registration: 1061932

3.0 Device Name(s)/Classification Name and Number

Device Trade Name(s): tetraCXP SYSTEM for the Cytomics FC 500 with CXP Software

Classification Name and Number: Automated differential cell counter ; 21 CFR 864.5220

4.0 Device Classification

The Hematology Panel has classified Automated differential cell counters as Class II, (81 GKZ) devices.

5.0 Section 514 Compliance

This Abbreviated 510(k) submission is prepared in accordance with FDA publication : The New 510(k) Paradigm: Alternate Approaches to Demonstrating Substantial Equivalence in Premarket Notifications-Issue Date: March 20, 1998. It claims compliance with the FDA publication: Class II Special Controls Guidance Document: Premarket Notifications for Automated Differential Cell Counters for Immature or Abnormal Blood cells; Final Guidance for Industry and FDA- Issue Date: December 4, 2001.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

MAY 21 2003

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

Re: k030828
Trade/Device Name: tetraCXP SYSTEM for the Cytomics FC 500 with CXP Software
Regulation Number: 21 CFR § 864.5220
Regulation Name: Automated differential cell counter
Regulatory Class: II
Product Code: GKZ
Dated: March 13, 2003
Received: March 14, 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

K030828

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

Device: tetraCXP SYSTEM for the Cytomics FC 500 with CXP Software

The tetraCXP Software for Cytomics FC 500 flow cytometry systems and CYTO-STAT tetraCHROME™ CD45-FITC/CD4-RD1/CD8-ECD/CD3-PC5 and CYTO-STAT tetraCHROME™ CD45-FITC/CD56-RD1/CD19-ECD/CD3-PC5 Monoclonal Antibody Reagents combine four-color fluorescent monoclonal antibody reagents, quality control reagents, an optional absolute count reagent, and software for automated analysis of lymphocyte populations in whole blood using Cytomics FC 500 flow cytometry systems with CXP Software.

The system with CYTO-STAT tetraCHROME CD45-FITC/CD4-RD1/CD8-ECD/CD3-PC5 is intended "For In Vitro Diagnostic Use" and allows simultaneous identification and enumeration of total CD3+, total CD4+, total CD8+, dual CD3+/CD4+ and dual CD3+/CD8+ T lymphocyte population percentages and absolute counts.

The system with CYTO-STAT tetraCHROME CD45-FITC/CD56-RD1/CD19-ECD/CD3-PC5 is intended "For In Vitro Diagnostic Use" and allows simultaneous identification and enumeration of total CD3+ (T), CD19+ (B), and CD3-/CD56+ (NK) lymphocyte population percentages and absolute counts. This reagent reflects the distribution of the three major subsets comprising the lymphocyte population upon which other lymphocyte enumeration studies are based and provides the total lymphocyte percentage.

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)
Division of Clinical Laboratory Devices
510(k) Number K030828