K081526

510(k) Summary
FlowCARE™ TLG Reagent

AUG 14 2008

1.0 **Submitted By:**

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Beckman Coulter, Inc.
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2.0 **Date Submitted:**
May 30, 2008

3.0 **Device Name(s):**

3.1 **Proprietary Names**
FlowCARE™ TLG Reagent

3.2 **Classification Name**
Automated differential cell counter
(21 CFR § 864.5220)

4.0 **Predicate Devices:**

Candidate	Predicates	Manufacturer	Docket Number
FlowCARE™ TLG Reagent	tetraONE™ SYSTEM for EPICS XL Flow Cytometry SYSTEM with CYTO-STAT© tetraCHROME™ CD45-FITC/CD4-RD1/CD8-ECD/CD3-PC5 Monoclonal Antibody Reagent	Beckman Coulter, Inc.	K990172

5.0 **Description:**
The FlowCARE™ TLG Reagent consists of a four-color antibody reagent composed of CD45-FITC, CD4-PE, CD8-ECD, and CD3-PC5. The assay is performed on the EPICS XL or suitably equipped flow cytometer using appropriate quality control reagents in combination with an optional absolute

count reagent, Flow-Count™ Fluorospheres, for determination of CD3+, CD3+CD4+, and CD3+CD8+ absolute counts as a single platform measurement, or in combination with a White Blood Cell Count from a hematology analyzer as a dual platform measurement.

6.0 **Intended Use:**

The FlowCARE TLG Reagent kit combines four fluorescent labeled monoclonal antibodies in a single reagent formulation. It is intended "For In Vitro Diagnostic Use" for the enumeration of CD3+, CD3+CD4+ and CD3+CD8+ absolute cell count and CD3+, CD3+CD4+ and CD3+CD8+ lymphocyte percentage in combination with a White Blood Cell (WBC) Count from a hematology instrument as a dual platform measurement, or independently when used in combination with Flow-Count™ Fluorospheres as a single platform measurement.

The FlowCARE TLG Reagent is designed for use on the COULTER® EPICS™ XL™/XL-MCL™ or a suitably equipped flow cytometer with a 488 nm laser capable of detecting light scatter (forward and side) and a minimum of four-color fluorescence emission detectable in the following ranges: 504 - 541 nm, 568 – 590 nm, 610 – 635 nm, and 660 – 680 nm. Users should refer to the manufacturer's instrument manuals for specific instructions for setting PMT voltages and fluorescence compensation prior to analysis.

7.0 **Comparison to Predicate(s):**

Comparison	Characteristic	tetraONE System for EPICS XL Flow Cytometry System (Predicate)	FlowCARE TLG Reagent
Similarities	Intended Use	Enumeration of three major T-lymphocyte subset populations (CD3+, CD3+CD4+, CD3+CD8+)	Same
	Analytical Instrumentation	Deployed on EPICS® XL-MCL™ flow cytometer	Deployed on EPICS® XL-MCL™ flow cytometer or suitably equipped flow cytometer
	Analysis Reagents	Uses CYTO-STAT® tetraCHROME™ CD45-FITC/CD4-RD1/CD8-ECD/CD3-PC5	CD45-FITC, CD4-PE (RD1), CD8-ECD, and CD3-PC5 monoclonal dye conjugates are identical to CD45-FITC/CD4-RD1/CD8-ECD/CD3-PC5 tetraCHROME™ reagent components

Comparison	Characteristic	tetraONE System for EPICS XL Flow Cytometry System (Predicate)	FlowCARE TLG Reagent
	Analysis Reagents	Uses Flow-Count™ Fluorospheres absolute count reagent	Same
	Setup Reagents	• Flow-Set™ Fluorospheres • CYTO-COMP™ Cell Kit • CYTO-COMP™ Reagent Kit	Same or equivalent reagents
	QC Reagents	• IMMUNO-TROL™ Control Cells • IMMUNO-TROL™ Low Control Cells	Same or equivalent reagents
Differences			
	Analysis Software	System II™ Automated analysis using cellSTAT 3D™ algorithm	Manual analysis using customer created protocols according to package insert
	Specimen Age	• ≤ 6 hours (with automated software) • ≤ 72 hours (without automated software, tetraCHROME CD45-FITC/CD4-RD1/CD8-ECD/CD3-PC5)	≤ 120 hours (5 days)* * The specimen age limit for dual platform measurement is dependent upon the claims for the hematology analyzer but not to exceed five days.

8.0 Summary of Performance Data:

Accuracy, precision, and linearity studies were conducted and demonstrated acceptable performance per the manufacturer specifications. 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

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

AUG 14 2008

Beckman Coulter, Inc.
c/o Ms. Nancy Nadler
Staff Regulatory Affairs Specialist
11800 SW 147 Ave, M/C: 31-B06
Miami, FL 33196-2500

Re: k081526
Trade/Device Name: FlowCARE™ TLG Reagent
Regulation Number: 21 CFR 864.5220
Regulation Name: Automated differential cell counter
Regulatory Class: Class II
Product Code: GKZ
Dated: May 30, 2008
Received: June 02, 2008

Dear Ms. Nadler:

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 advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of In Vitro Diagnostic Device Evaluation and Safety at (240) 276-0450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (240) 276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at (240) 276-3464. 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 (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Maria M Chan

Maria M. Chan, Ph.D.
Acting Division Director
Division of Immunology and Hematology Devices
Office of In Vitro Diagnostic Device Evaluation
and Safety
Center for Devices and Radiological Health

Enclosure

Indication for Use

510(k) Number (if known): K081526

Device Name: FlowCARE™ TLG Reagent

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Prescription Use __X__ (21 CFR Part 801 Subpart D) And/Or Over the Counter Use ____ (21 CFR Part 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE; CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Device Evaluation and Safety (OIVD)

Maria M Chan

Division Sign-Off
Office of In Vitro Diagnostic Device
Evaluation and Safety

510(k) K081526