K081213

510(k) Summary

1.0: Submitted By:

AUG 14 2008

BD Biosciences
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San Jose, CA 95131

Contact:
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Submission Date:
April 28, 2008

2.0: Device Name:

a) BD FACSCount™ CD4 Reagents
b) 21CFR 862.5220Automated Differential Cell Counter (GKZ Class II)

3.0: Intended Use:

BD FACSCount CD4 reagents are used to enumerate the absolute counts of CD4 T lymphocytes and determine the percentage of lymphocytes that are CD4 T lymphocytes in unlysed whole blood (CD4 count and CD4 percentage). The reagents are for in vitro diagnostic use on a BD FACSCount instrument.

4.0: Basic description of the device:

BD FACSCount CD4 reagents are intended for use in enumerating the absolute counts of CD4 T lymphocytes and the percentage of lymphocytes that are CD4 T lymphocytes in unlysed whole blood using the BD FACSCount instrument system. The product offers a single test that requires one convenient, ready-to-use reagent tube labeled CD4. It is intended for use on a BD FACSCount instrument.
The reagent kit consists of the following components:

- 50 reagent tubes of CD4 PE/CD14 PE-Cy5/CD15 PE-Cy5/fluorescent nuclear dye and counting reference beads
- 65 reagent tube caps
- One 5-mL vial of 5% formaldehyde in phosphate-buffered saline (PBS), used as fixative solution

5.0: Predicate Device:

BD FACSCount CD4 Reagents is substantially equivalent to BD Tritest CD3/CD4/CD45 with and without BD Trucount absolute count tubes (K071143 and K071141) for the enumerating the absolute counts of CD4 T lymphocytes and the percentage of lymphocytes that are CD4 T lymphocytes in unlysed whole blood.

6.0 Comparison to the Predicate:

Similarities and Differences:

Characteristic	BD TriTEST CD3/CD4/CD45 with and without BD Trucount absolute count tubes on BD FACSCalibur (Predicate)	BD FACSCount CD4 Reagents on BD FACSCount (New)
Intended Use	BD TriTEST CD3/CD4/CD45 is a three color direct immunofluorescence reagent for use with a suitably equipped flow cytometer to identify and determine the percentages and absolute counts of mature human T lymphocytes (CD3+), helper/inducer (CD3+CD4+) T lymphocytes in erythrocyte lysed whole blood. When used with BD Trucount tubes, absolute counts of these populations can be enumerated from a single tube. This BD Tritest reagent and BD Trucount tubes can be used with the BD FACSLoader. The reagent can be used with or without an isotype control.	BD FACSCount CD4 Reagents are two color direct immunofluorescence reagent for identifying and determining absolute counts in cells/ul and percentage of CD4+ T lymphocytes in unlysed whole blood.
Device classification and product code	Class II 81 GKZ Regulation 21 CFR §864.5220	Same
Reagent	BD TriTEST CD3FITC/CD4PE/CD45PerCP	BD FACSCount CD4 Reagents CD4PE/CD14PE-Cy5/CD15PECy5/fluoresenct nuclear dy
Absolute count beads	Trucount Absolute Count beads	Known number of reference beads included in reagent
ControlBeads	None	BD FACSCount Controls (low/mid/high)
Sample type	Whole blood preserved with EDTA, heparin, or ACD-Solution A	Whole blood preserved with EDTA only
System electronics	Analog	*Same*
Fluorescence Scale *(Display)*	Calibur 1024 log scale or 10^4 linear scale	*N/A – Customer does not see the dot-plot*
Cytometer setup	Uses FACSComp software with BD Calibrite™ Beads to set up FL2.	*None – no customer set up required*
Sample Analysis:	Automatic analysis. User is able to adjust the gating to optimize.	*Automatic analysis with no user intervention*
Dynamic Range	68 - 7.2x10^3 cells/ul CD4/CD3 positive cells	*CD4 absolute count of: 50-5000cells/ul CD4 percentage of : 5-65%*
Results	*Samples are reported as CD4/CD3 positive cells/ul and CD4/CD3 % positives of Lymphocytes*	*Samples are reported as CD4 cells/ul and CD4% of Lymphocytes*

7.0: Summary of Performance Data:

Equivalency for the candidate product has been demonstrated through method comparison, precision, linearity stain stability, and reagent stability studies.

A) Summary of Method Comparison study results:

Parameter	n	R^2	Slope	Intercept
CD4 Absolute Count (cells/uL)	101	0.981	0.971	12.695
CD4 Percentage (%)	99	0.99	0.999	-0.391

B) Summary of System Precision study results:

Within-device and within-run precision of CD4 absolute counts (cells/uL)

	Low control CV (cell/ul)	Normal control CV (cells/ul)
Within device	4.82	4.28
Within run	4.04	3.46

Within-device and within-run precision of CD4 percentage (cells/uL)

	Low control CV (cell/ul)	Normal control CV (cells/ul)
Within device	0.38	1.28
Within run	0.35	1.15

C) Summary of System Linearity study results:

Linearity was assessed and observed to be linear within the reportable CD4+ absolute count range (50 – 5000 cells/ul).

D) Summary of Stained Sample Stability (*Age of Stain)* study:

Age of blood and age of stained sample were assessed and observed to be stable up to 24 hours of age of blood and up to 48 hours of age of stain.

E) Summary of Reagent Stability (Shelflife) study:

Reagents were assessed and the Kit was observed to be stable up to 15 month. Expiration dating may be extended in the future if ongoing product stability testing supports the extension.

This Summary of safety and effectiveness is being submitted in accordance with the requirements of compliance with SMDA 1990 and 21 CFR807.92.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

AUG 14 2008

BD Biosciences
c/o Mr. Nobuko Nakajima
Senior Regulatory Affairs Specialist
2350 Qume Drive
San Jose, CA 95131

Re: k081213
Trade/Device Name: BD FACSCount™ CD4 Reagents
Regulation Number: 21 CFR 864.5220
Regulation Name: Automated differential cell counter
Regulatory Class: Class II
Product Code: GKZ
Dated: July 30, 2008
Received: July 31, 2008

Dear Mr. Nakajima:

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

Indications for Use

510(k) Number (if known): K081213

Device Name: BD FACSCount™ CD4 Reagents

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Prescription Use __X__ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Maria M Chan

Division Sign-Off

Office of In Vitro Diagnostic
Device Evaluation and Safety

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