510(k) Summary

SEP 14 2006

This summary of 510(k) safety and effectiveness is being submitted in accordance with the requirements of Safe Medical Devices Act of 1990 and 21 CFR 807.92.

The assigned 510(k) number is K062087

Submitter Information

Submitter: BD Biosciences
2350 Qume Drive
San Jose, CA 95131

Contact: Carter Navarro
Regulatory Affairs Specialist
Tel.: (408) 954-2469
Fax: (408) 954-2495
carter_navarro@bd.com

Summary Date: July 20, 2006

Device Name / Classification

Name: BD FACSCanto II system

Classification: Class II (21 CFR 864.5220) – Automated differential cell counter

Substantially Equivalent / Predicate Device

The BD FACSCanto II system is substantially equivalent to the BD FACSCanto system with BD FACSCanto clinical software and BD FACSDiva software (premarket notifications K041074 and K040725).

Device Description

The BD FACSCanto II system is comprised of a flow cytometer, a fluidics cart, and a computer workstation. The fluidics cart contains operational fluids, the flow cytometer acquires and analyzes the sample, and the computer displays and prints the analysis. The flow cytometer utilizes three subsystems: fluidics, optics, and electronics. The computer workstation runs two software packages: BD FACSCanto clinical software for automatic immunophenotyping of assays prepared using the lyse/no-wash method, and BD FACSDiva software for manual immunophenotyping of assays prepared using the lyse/wash method.

The BD FACSCanto II system can optionally be used with the BD FACS Loader for automatic sample introduction, a standalone barcode reader for data input into BD FACSCanto clinical software, and with the BD FACS Sample Prep Assistant II for automatic sample preparation of assays utilizing the lyse/no-wash method.

The BD FACSCanto II system is a modification of the BD FACSCanto system, bearing the same intended use, indications for use, and operating principle as its predicate device. Modifications have been made to the fluidics, optics, and electronics subsystems. Changes were also made to the sample introduction system, the BD FACS Loader option, and to the two software applications. These changes have been made to enhance the system's usability.

Intended Use

The BD FACSCanto II system is intended for use as an in vitro diagnostic device for the identification and enumeration of lymphocyte subsets in human cells in suspension.

Technological Characteristics

The following summary table describes the similarities and differences between the BD FACSCanto II system and the BD FACSCanto system.

Characteristic	**BD FACSCanto system** (predicate)	**BD FACSCanto II system** (new family member)
Intended use	In vitro diagnostic device for identification and enumeration of lymphocyte subsets in human cells in suspension using the lyse/wash and lyse/no-wash sample preparation methods for flow cytometry.	Same.
Device classification and product code	Automated Differential Cell Counter 21 CFR 864.5220 Product Code: GKZ	Same.
Lasers	Red – 488-nm argon ion Blue – 635-nm diode	Same.
Optics	Laser light delivered by fiber optics and prisms. Emitted light delivered by collection and fiber optics.	Same.
Electronics	Multiple electronics boards containing acquisition electronics components.	One consolidated acquisition electronics board.
Maximum parameter detection	Eight (FSC, SSC, and six fluorophores).	Same.
Software	BD FACSCanto clinical software v.1.0 or higher and BD FACSDiva software v.4.0 or higher.	BD FACSCanto clinical software v.2.1 or higher and BD FACSDiva software v.5.0.1 or higher.
Instrument setup and quality control	Automated setup using BD FACSCanto clinical software and BD FACS 7-color setup beads.	Same.
Sample introduction	Manual, or automated with the optional BD FACS Loader.	Same.
Sample preparation	Manual pipetting for the lyse/wash or lyse/no-wash methods, or automated with the BD FACS Sample Prep Assistant II for the lyse/no-wash method.	Same.

Characteristic	BD FACSCanto system (predicate)	BD FACSCanto II system (new family member)
Sample type	Whole blood.	Same.
Accessories	Optional standalone barcode reader.	Same.

Performance Data

Study	Study Design	Results
Method Comparison	Based on *Method Comparison and Bias Estimation Using Patient Samples*, CLSI document EP9-A2.	The BD FACSCanto II system demonstrated comparable accuracy relative to the predicate when running the BD Multitest IMK kit and BD Multitest 6-color TBNK assays.
Precision	Based on *Evaluation of Precision Performance of Clinical Chemistry Devices*, CLSI document EP5-A2.	The BD FACSCanto II system demonstrated acceptable precision when running the BD Multitest IMK kit and BD Multitest 6-color TBNK assays.
Linearity	Based on *Evaluation of the Linearity of Quantitative Measurement Approaches: A Statistical Approach*, CLSI document EP6-A.	The BD FACSCanto II system demonstrated acceptable linearity when running the BD Multitest IMK kit and BD Multitest 6-color TBNK assays.
% Agreement	Based on *User Protocol for Evaluation of Qualitative Test Performance*, CLSI EP12- A.	The BD FACSCanto II system demonstrated acceptable % agreement when running the BD HLA-B27 assay.
Reproducibility	Pairs (positive & negative) of specimens were tested in duplicate by multiple operators, twice daily for multiple operating days across different instruments.	The BD FACSCanto II system demonstrated acceptable reproducibility when running the BD HLA-B27 assay.
Carryover	Based on recommendations contained in *Class II Special Controls Guidance Document: Premarket Notifications for Immature or Abnormal Blood Cells; Final Guidance for Industry and FDA*, December 4, 2001.	The BD FACSCanto II system demonstrated acceptable carryover.

Conclusions from Performance Data

The BD FACSCanto II system demonstrates substantial equivalence to the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

SEP 1 4 2006

BD Biosciences
Immunocytometry Systems
2350 Qume Dr.
San Jose, CA 95131
ATTN: Carter Navarro

Re: k062087
Trade/Device Name: BD FACSCanto II flow cytometer
Regulation Number: 21 CFR 864.5220
Regulation Name: Automated Differential Cell Counter
Regulatory Class: II
Product Code: GKZ
Dated: July 20, 2006
Received: July 24, 2006

Dear Mr. Navarro:

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.

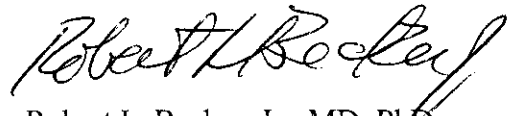
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish 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 (240) 276-0484. 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 (240) 276-3150, or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html.

Sincerely yours,



Robert L. Becker, Jr., MD, PhD
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: K062087
(if known)

Device Name: BD FACSCanto II System

Indications for Use:

- Immunophenotyping in clinical laboratories, using previously cleared in vitro diagnostic assays for flow cytometry.
- Identification and enumeration of lymphocyte subsets in human cells in suspension.
- For in vitro diagnostic use.
- For use with or without the BD FACS Sample Prep Assistant II.

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 –
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Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

Division Sign-Off

Office of In Vitro Diagnostic Device Evaluation and Safety

510(k) K062087