FEB 2 2 2005



# Section 1.3.
# 510(k) Summary

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 K050191

## Submitter Information (21 CFR 807.92(a)(1))

Submitter: BD Biosciences
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**Summary Date:** January 26, 2005

## Device Name / Classification (21 CFR 807.92(a)(2))

Name: BD FACSCanto system with BD FACSCanto clinical software

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

## Substantially Equivalent/Predicate Device (21 CFR 807.92(a)(3))

The BD FACSCanto system with BD FACSCanto clinical software, using the BD FACS Sample Prep Assistant II ("SPA II"), is substantially equivalent to the BD FACSCanto system with BD FACSCanto clinical software using manual pipetting. The SPA II and manual pipetting are used for the same sample type and result in similar performance characteristics.

## Device Description (21 CFR 807.92(a)(4))

The BD FACSCanto system with BD FACSCanto clinical software is a flow cytometry system designed for analyzing samples prepared with the lyse / no-wash method. The BD FACS Sample Prep Assistant II is a microprocessor-controlled pipetting and diluting system which automatically prepares whole blood samples using the lyse / no-wash sample preparation method for flow cytometry. Used as an accessory to the BD FACSCanto flow cytometer, the SPA II combines fluidic, optic, robotic, and electronic components to automatically prepare samples for acquisition and analysis with a flow cytometer.

The SPA II pierces the sample tube cap to withdraw sample, aliquots blood and reagent into daughter tubes, and mixes the sample according to preprogrammed or custom protocols. The device also adds lysing solution and automates cleaning protocols. The unit consists of an enclosure, one robotic pipetting module moving in the X/Y/Z axes, a power supply, a central controller unit, fluid pumps, and a barcode reader.

## Intended Use (21 CFR 807.92(a)(5))

The BD FACSCanto system with BD FACSCanto clinical software when used with the BD FACS Sample Prep Assistant II is intended for use as an in vitro diagnostic device for identification and enumeration of lymphocyte subsets in human cells in suspension using a lyse / no-wash sample preparation method for flow cytometry. This is the **same intended use** as previously cleared for the BD FACSCanto system with BD FACSCanto clinical software.

## Technological Characteristics (21 CFR 807.92(a)(6))

The following summary table describes the similarities and differences between the BD FACSCanto system with BD FACSCanto clinical software using manual pipetting versus automated sample preparation using the BD FACS Sample Prep Assistant II.

| Characteristic | BD FACSCanto system with BD FACSCanto clinical software using manual pipetting (predicate) | BD FACSCanto system with BD FACSCanto clinical software using the BD FACS Sample Prep Assistant II |
|---|---|---|
| Intended Use | An in vitro diagnostic device for identification and enumeration of lymphocyte subsets in human cells in suspension using a lyse no-wash sample preparation method for flow cytometry. | Same. |
| Sample Type | Whole blood | Same. |
| Device Classification and Product Code | Automated Differential Cell Counter<br>21 CFR 864.5220<br>Product Code: GKZ | *Complete System*<br>Same.<br><br>*SPA II as stand-alone:*<br>Pipetting and Diluting Station for Clinical Use<br>21 CFR 862.2750<br>Product Code: JQW |
| Preparation Method | Manual pipetting. | Automated. |

The SPA II is a modification of Tecan Systems' Mini Sample Processor (MSP) 9250, an OEM sister device of the MSP 9500 (cleared by FDA on April 21, 1997, under 510(k) number K970616). Substantial equivalence is not being claimed to the MSP 9500, since that device's product code (JQW) has since been designated as Class I, exempt from 510(k), and since the intended use of the SPA II brings it under the Class II designation of the incorporating BD FACSCanto system.

A brochure from Tecan Systems on these OEM sample preparation devices is provided in Section 2 for information only.

## Performance Data (21 CFR 807.92(b)(1) and (2))

| Study | Study Design | Results |
|---|---|---|
| Accuracy | Based on *Method Comparison and Bias Estimation Using Patient Samples; Approved Guideline*, NCCLS document EP9-A. | The BD FACSCanto system with the BD FACS Sample Prep Assistant II demonstrated comparable accuracy relative to the predicate. |
| Precision | Based on *Evaluation of Precision Performance of Clinical Chemistry Devices; Approved Guideline*, NCCLS document EP5-A. | The BD FACSCanto system with the BD FACS Sample Prep Assistant II demonstrated acceptable system precision |
| Carryover | Based on recommendations contained in *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*, December 4, 2001. | The BD FACSCanto system with the BD FACS Sample Prep Assistant II demonstrated acceptable system carryover. |

## Conclusions from Performance Data (21 CFR 807.92(b)(3))

The BD FACSCanto system with BD FACSCanto clinical software using the BD FACS Sample Prep Assistant II demonstrates substantial equivalence to the predicate method.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

FEB 2 2 2005

Mr. Carter Navarro
Regulatory Affairs Specialist
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2350 Qume Drive
San Jose, California 95131

Re: k050191
Trade/Device Name: BD FACSCanto System with BD FACSCanto Clinical Software
Regulation Number: 21 CFR § 864.5220
Regulation Name: Automated Differential Cell Counter
Regulatory Class: II
Product Code: GKZ
Dated: January 26, 2005
Received: January 27, 2005

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 (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html

Sincerely yours,

Robert L. Becker, Jr., MD, Ph.D
Director
Division of Immunology and Hematology
Office of *In Vitro* Diagnostic Device
Evaluation and Safety
Center for Devices and
Radiological Health

Enclosure

# Section 1.2.
# Indications for Use

510(k) Number (if known): K050191

Device Name: BD FACSCanto System with BD FACSCanto Clinical Software

*Indications for Use:*

- Immunophenotyping in clinical laboratories, using previously cleared IVD assays for flow cytometry that utilize the lyse no-wash sample preparation method.
- Immunophenotyping of lymphocyte subsets including $CD3^+CD8^+$, $CD3^+CD4^+$, $CD3^-CD16^+$ and/or $CD56^+$, $CD3^-CD19^+$, and $CD3^+$.
- 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

Page 1 of ___

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