DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

OCT 1 2004

Ms. Kim Fonda
Senior Regulatory Affairs Specialist
Becton Dickinson Immunocytometry Systems
2350 Qume Drive
San Jose, California 95131

Re: k041074
Trade/Device Name: BD FACSCanto System with BD FACSCanto software
Regulation Number: 21 CFR § 864.5220
Regulation Name: Automated differential cell counter
Regulatory Class: II
Product Code: GKZ
Dated: August 11, 2004
Received: August 13, 2004

Dear Ms. Fonda:

This letter corrects our signed letter of September 17, 2004, regarding the typo to the device name. 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,

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

Enclosure

SEP 17 2004

Attachment D
510(k) Summary

BD FACSCanto with BD FACSCanto software 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 **K041074**.

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

Submitter: Becton Dickinson Immunocytometry Systems
2350 Qume Drive
San Jose, CA 95131

Contact: Kim Fonda
Sr. Regulatory Affairs Specialist
(408) 954-2329
(408) 954-2495 (FAX)
kim_fonda@bd.com

Summary date: April 22, 2004

Device Name and Classification (21 CFR 807.92(a)(2))

Name: BD FACSCanto™ System with BD FACSCanto 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 software is substantially equivalent to the BD FACSCalibur™ with 4-color option for immunophenotyping using BD Multitest reagents and BD Multiset software. The BD FACSCalibur 4-color instrument was cleared with FACSComp Software and CaliBRITE Beads by the Center for Devices and Radiological Health, under K973483 on 2/17/98. The BD FACSCanto with BD FACSCanto software and BD FACSCalibur have similar intended uses, measure the same sample types and have similar performance characteristics.

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

The BD FACSCanto System with BD FACSCanto software is comprised of a flow cytometer, a fluidics cart, and a computer. 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 sub-systems; fluidics, optics and electronics. It contains two software packages, one for manual immunophenotyping and one for automatic immunophenotyping, and is compatible with the BD FACS Loader for automatic sample introduction.

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

The BD FACSCanto System with BD FACSCanto software 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.

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

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

Characteristic	**FACSCalibur System** (predicate)	**BD FACSCanto System** (new family member)
Intended Use	For identification and enumeration of leucocyte subsets in human cells in suspension	For identification and enumeration of lymphocyte subsets in human cells in suspension using a lyse no-wash sample preparation method for flow cytometry
Device classification and product code	Automated Differential Cell Counter, 21 CFR 864.5220 Product Code: GKZ	Same
Lasers	Blue—488 nm argon ion Red—635 nm diode laser	488 nm solid state 633 nm HeNe
Detectors	1 FSC photodiode 1 SSC photomultiplier tube (PMT) 4 fluorescence detector PMTs	Same FSC Same SSC Same 4 plus 2 additional fluorescence detector PMTs
Optics	FACSCalibur flow cell Laser light delivered by mirrors, prisms and lenses Emitted light delivered by mirrors	Same Laser light delivered by fiber optics, prisms and lasers Emitted light delivered by collection and fiber optics

Characteristic	**FACSCalibur System** (predicate)	**BD FACSCanto System** (new family member)
Electronics	Analog	Digital
Automated sample introduction	FACS Loader: K953302 11/20/95	Same
Computer platform	MacIntosh	PC

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

Study	**Study Design**	**Results**
Accuracy	Based on NCCLS document EP9-A2. (September 2002)	The BD FACSCanto with BD FACSCanto software demonstrated comparable accuracy relative to the predicate.
Precision	Based on NCCLS document, EP5-A. (February 1999)	The BD FACSCanto with BD FACSCanto software demonstrated acceptable system precision.
Linearity	Based on NCCLS document, EP6-A. (April 2003)	The BD FACSCanto with BD FACSCanto software demonstrated acceptable system linearity.

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

The BD FACSCanto System demonstrates substantial equivalence to the predicate device.

Indications for Use

510(k) Number: K041074

Device Name: BD FACSCanto System with BD FACSCanto 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 $CD3^+$.

Clinical Significance:

- For In Vitro Diagnostic Use.

Prescription Use ___X___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE
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Concurrence of CDRH, Office of Device Evaluation (ODE)

Division Sign-Off

Office of In Vitro Diagnostic Device Evaluation and Safety

510(k) K041074

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