SEP 1 0 2004

510(k) Summary

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

The assigned 510(k) number is K040026.

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

Submitter: BD Biosciences Immunocytometry Systems, a business unit of
Becton, Dickinson and Company
2350 Qume Drive
San Jose, CA 95131-1807

Contact: Cindy Morrow
Sr. Regulatory Specialist
(408) 954-2694

Summary date: June 17, 2004

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

Name: BD FACS™ 7-color setup beads

Classification: Class I (Quality Control beads)

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

BD FACS™ 7-color setup beads are substantially equivalent to CaliBRITE™ beads cleared in K000897 (05/05/2000), K973483 (02/17/1998), K961623 (06/07/1996), and K925274 (09/30/1994).

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

BD FACS 7-color setup beads are intended for use on the BD FACSCanto flow cytometer equipped with a 488-nm blue laser, a 633-nm red laser, and six fluorescence detectors. BD FACS 7-color setup beads are provided as a lyophilized pellet contained in 25 individually packaged test tubes along with a bottle of BD FACS setup bead diluent.

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

For in vitro diagnostic use on a BD FACSCanto flow cytometer with BD FACSCanto software. The beads are used to adjust fluorescent detector voltages, to set fluorescence compensation, and to monitor daily instrument performance.

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

BD FACS 7-color setup beads are lyophilized and are rehydrated with BD FACS setup bead diluent or BD FACS bead dilution buffer. The beads are substantially equivalent to liquid BD CaliBRITE beads for flow cytometry setup. The product is composed of 25 test tubes, each containing a lyophilized pellet of beads packaged in air-tight single-use pouches. A bottle of BD FACS setup bead diluent is provided for use in rehydration of the beads prior to their use for setting up a suitably equipped flow cytometer.

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

Performance of this product was established by testing at Becton Dickinson Immunocytometry Systems laboratories in San Jose, California.

Studies performed:

- Stability

  Storage stability of beads was determined to be 7 months at 2-8°C.
  Once diluted, the mixed-bead preparation is stable for 1 hour at 20-25°C or 8 hours at 2-8°C.

- Reproducibility

  Between three bead lots
  Reproducibility was found to be equivalent to the predicate device.

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

The results of the design verification studies demonstrate that the device is as safe and effective as the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

SEP 1 0 2004

Ms. Cindy Morrow
Sr. Regulatory Affairs Specialist
Becton Dickinson Immunocytometry Systems
2350 Qume Drive
San Jose, CA 95131

Re: k040026
Trade/Device Name: BD FACS 7-Color Setup Beads
Regulation Number: 21 CFR 864.5220
Regulation Name: Automated differential cell counter
Regulatory Class: Class II
Product Code: GKZ
Dated: August 23, 2004
Received: August 24, 2004

Dear Ms. Morrow:

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

Indications for Use Statement

510(k) Number: K040026

Device Name: BD FACS 7-Color Setup Beads

Indications for Use:

- The beads are for use on a BD FACSCanto™ flow cytometer equipped with BD FACSCanto software.
- The beads are used to adjust detector voltages, to set fluorescence compensation and to monitor daily instrument performance.

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

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Office of In Vitro Diagnostic Device Evaluation and Safety

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