K973483

Attachment G FEB 17 1998

510(k) Summary

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

Submitter: Becton Dickinson Immunocytometry Systems
2350 Qume Drive
San Jose, CA 95131-1807

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

Summary date: December 17, 1997

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

Name: CaliBRITE™ APC beads, CaliBRITE 4 kit (unlabeled, FITC-, PE-, PerCP- and APC-labeled CaliBRITE beads), and FACSComp™ software

Classification: Accessory to a Class II Device

Predicate Device (21 CFR 807.92(a)(3))

CaliBRITE™ 4 kit and FACSComp™ software is substantially equivalent to CaliBRITE™ 3 kit (unlabeled, FITC-, PE-, and PerCP-labeled CaliBRITE beads) and FACSCOMP™ software, K961623, cleared to market on June 7, 1996.

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

Becton Dickinson FACSComp software and the CaliBRITE 4 bead kit (FACSComp/CaliBRITE 4) are intended for use on the Becton Dickinson flow cytometers, FACSort™ or FACSCalibur™, equipped with the FL4 Option. FACSComp/CaliBRITE 4 are used to check laser alignment, optimally adjust instrument settings, monitor sensitivity, and to set the compensation of flow cytometers for spectral overlap of fluorescent dyes. FACSComp/CaliBRITE 4 are used to set up and verify the separation of system noise from forward and side scatter and to set fluorescence compensation on flow cytometers with four fluorescence (FL) channels FACSComp/CaliBRITE 4 is used for setting the photomultiplier tube (PMT) voltages, setting the fluorescence compensation, and checking instrument sensitivity on flow cytometers. This product is recommended for instrument set up prior to running Becton Dickinson software applications for flow cytometers. The CaliBRITE beads are provided as a separate vial of CaliBRITE APC beads and the four-vial CaliBRITE 3 kit, comprised of unstained, FITC-, PE- and PerCP-labeled beads.

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

For flow cytometer set up and monitoring of instrument performance prior to performing reticulocyte ennumeration or immunophenotyping applications. Flow cytometry has been found useful in monitoring some forms of immune disease.

Comparison to Predicate Device (21 CFR 807.92(a)(6))

FACSComp/CaliBRITE 4 is substantially equivalent to FACSComp software and the CaliBRITE 3 kit, (K961623). The product is composed of four vials of beads that are identical to that of the predicate, and the new CaliBRITE APC vial, containing polystyrene beads conjugated with APC that are used to set up the FL4 Option.

The term "substantial equivalence" as used in this 510(k) notification is limited to the definition of substantial equivalence as found in the Federal Food, Drug, and Cosmetic Act, as amended and as applied under 21 CFR 807, Subpart E under which a device can be marketed without pre-market approval or reclassification. A determination of substantial equivalency under this notification is not intended to have any bearing whatsoever on the resolution of patent infringement suits or any other patent matters. No statements related to, or in support of substantial equivalence herein shall be construed as an admission against interest under the US Patent Laws or their application by the courts.

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

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

Several studies were performed:

- Stability was measured

  Storage stability of beads was determined to be 8 months under the conditions of use.

  Once diluted, the two-bead preparation of CaliBRITE APC and unlabeled beads (Tube A) is stable for 8 hours. The five-bead preparation (Tube B) is stable for 1 hour after dilution.

- Reproducibility was measured

  Between bead lots.

  Within instrument across two computer platforms.

  Within the set up options of lyse and wash (L/W) and lyse no wash (LNW) across colors.

  Between manual and automated 4-color LNW setup options.

  Within instrument over 20 days.

  Reproducibility was found to be equivalent to the predicate device.

Performance Data–Conclusions (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.

Cindy Morrow.
Sr Regulatory Specialist

12/17/97
Date

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

Cindy Morrow
Sr. Regulatory Specialist
Becton Dickinson Immunocytometry Systems
2350 Qume Drive
San Jose, California 95131-9475

FEB 17 1998

Re: K973483
- Trade Name: Becton Dickinson Immunocytometry Systems (BDIS) CaliBRITE™ APC (Allophycocyanin) beads, CaliBRITE 4 kit (unlabeled, FITC, PE, PerCP, and APC labeled CaliBRITE beads), and FACSComp™ software.

Regulatory Class: II
Product Code: GKZ
Dated: December 17, 1997
Received: December 18, 1997

Dear Ms. Morrow:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to 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). 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 (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirement, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

Under the Clinical Laboratory Improvement Amendments of 1988 (CLIA-88), this device may require a CLIA complexity categorization. To determine if it does, you should contact the Centers for Disease Control and Prevention (CDC) at (770)488-7655.

This letter will allow you to begin marketing your device as described in your 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 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4588. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll free number (800) 638-2041 or at (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsmamain.html"

Sincerely yours,

Steven Gutman

Steven I. Gutman, M.D., M.B.A.
Director
Division of Clinical
Laboratory Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K973463

Device Name: _____

Indications For Use:

Attachment A—**Indications for Use:**

For the FACS® family of flow cytometers (FACScan, FACSort and FACSCalibur).

An accessory device for instrument setup prior to performing reticulocyte ennumeration and immunophenotyping.

For adjusting instrument settings: aligning the signal from the blue and the optional red laser (FL4 Option), setting the photomultiplier tube (PMT) voltages, and monitoring instrument performance over time.

For automatically setting the fluorescence compensation of the detectors to adjust for spectral overlap of fluorescent signals.

For monitoring the sensitivity of the side scatter (SSC) and fluorescence (FL1, FL2, FL3, and FL4) detectors and verifying adequate separation of system noise from forward scatter (FSC) signals.

For in vitro diagnostic use.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Clinical Laboratory Devices
510(k) Number K973463

Prescription Use ✓ OR **Over-The-Counter Use** ___
(Per 21 CFR 801.109)

(Optional Format 1-2-96)