MAR 11 1998

510(k) Summary

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21CFR807.92.

The assigned 510(k) number is K974360.

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: November 18, 1997

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

Name: MultiTEST CD3/CD8/CD45/CD4

Classification: Class II Device

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

MultiTEST CD3/CD8/CD45/CD4 reagent and TRUCOUNT absolute count tubes are substantially equivalent* to TriTEST CD3/CD8/CD45 (K970326), TriTEST CD3/CD4/CD45 (K965053), TRUCOUNT tubes (K970836) and MultiSET software (K963963).

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

The Becton Dickinson CD3 fluorescein isothiocyanate (FITC)/CD8 phycoerythrin (PE)/CD45 peridinin chlorophyll protein (PerCP)/CD4 allophycocyanin (APC) reagent is a four-color, direct immunofluorescence reagent for identifying and enumerating percentages of $CD3^+$ T Lymphocytes, $CD3^+CD4^+$ helper/inducer, and $CD3^+CD8^+$ suppresser/cytotoxic T-Lymphocyte subsets in erythrocyte-lysed whole blood. Each vial of reagent yields 50 tests. The reagent is intended for use on the Becton Dickinson FACSort™ or FACSCalibur™ flow cytometers equipped with the FL4 Option, the Apple Macintosh Quadra or PowerPC computer, and CELLQuest or MultiSET software. Daily instrument set-up requires CaliBRITE beads (unlabeled, FITC, PE, Per CP, and APC) and FACSComp software.

* 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.

The four-color method permits the identification and enumeration of helper/inducer and suppresser/cytotoxic T-Lymphocyte subsets using MultiSET software's single-tube fluorescence gating and automated quality control algorithms. A lymphocyte gate is drawn for the CD45+ leucocytes with low side scatter and the T-Lymphocyte subsets are provided as an absolute count or percentage of total lymphocytes.

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

MultiTEST CD3/CD8/CD45/CD4 reagent is a four-color reagent for identifying and enumerating $CD3^+$ T Lymphocytes, $CD3^+CD4^+$ helper/inducer, and $CD3^+CD8^+$ suppresser/cytotoxic T-Lymphocyte subsets by direct immunofluorescence. Subsets of T Lymphocytes are useful in managing immunodeficiency diseases. To characterize and monitor congenital or acquired immunodeficiencies, such as SCID or AIDS.

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

MultiTEST CD3/CD8/CD45/CD4 is a four-color reagent and TriTEST CD3/CD8/CD45 and TriTEST CD3/CD4/CD45 are three-color reagents. The three and four-color reagents all employ the same monoclonal antibody clones, however the CD4 antibody is conjugated to PE in the three-color reagent and to APC in the four-color reagent. The three-color reagent includes FITC, PE, and PerCP fluorescent dyes that are excited by the flow cytometer's blue (488-nm) argon-ion laser. The four-color reagent contains an additional APC fluorescent dye. The APC is excited by a red diode (635-nm) laser provided in Becton Dickinson's FL4 Option for the FACSort and FACSCalibur flow cytometers.

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

Performance of the product was established by testing at Children's Memorial Hospital, Chicago, Illinois; Covance Central Laboratory, Indianapolis, Indiana; Cleveland Clinic Foundation Cleveland, Ohio; or Becton Dickinson Immunocytometry Systems, San Jose, California.

Several studies were performed:

- Accuracy was determined by comparing results from lysed whole blood (LWB) specimens stained with both the three- and four-color reagents on the FACSCalibur. A total of 129 specimens, including 70 normals and 59 abnormals were obtained and analyzed at two clinical sites. Accuracy data demonstrated that MultiTEST CD3/CD8/CD45/CD4 is equivalent to TriTEST CD3/CD8/CD45 and TriTEST CD3/CD4/CD45.

- Within-site reproducibility was performed on LWB specimens from 3 normal and 6 abnormal donors across the range of low (100-350), medium (350-700), and high (>700) $CD4^+$ T cell counts (cells/μL). Each specimen was divided into 10 aliquots and then stained and analyzed using a FACSCalibur system. Results demonstrated acceptable within-site reproducibility.

- Across-site reproducibility was performed at three clinical sites on LWB specimens from a total of 15 normal and 31 abnormal donors across the same range of low, medium, and high $CD4^+$ T cell counts (cells/µL). Each specimen was divided into 5 aliquots and then stained and analyzed using a FACSCalibur system. Results demonstrated acceptable across site reproducibility.

- Stability studies were conducted at one site using samples from 10 normal and 20 abnormal donors. The studies assessed changes associated with the storage of whole blood prior to staining, changes as a result of time between staining and data acquisition, and the combined effect of time of storage and time after staining. Results demonstrate acceptable stability of samples prepared up to 48 hours after blood draw and stability of prepared samples up to 24 hours after preparation.

- Linearity and recovery was determined using blood specimens from 3 normal donors diluted to 5 different concentrations, ranging from 200 to 29,700 WBC/µL and from 100 to 9000 Lymphocytes/µL. Results indicate linear response over this range and acceptable recovery.

Comparison to Predicate Device (21 CFR 807.92(b)(3))

The results of the clinical studies demonstrate that the device is as safe and effective as the predicate device. The four-color MultiTEST CD3/CD8/CD45/CD4 reagent is substantially equivalent to the predicate three-color TriTEST CD3/CD4/CD45 and TriTEST CD3/CD8/CD45 reagents, in that they share the same intended uses and methodologies. Results demonstrate that the products yield essentially equivalent performance characteristics.

Cindy Morrow

Sr Regulatory Specialist

3/4/98

Date

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

Ms. Cindy Morrow
Sr. Regulatory Specialist
Becton Dickinson Immunocytometry Systems
2350 Qume Drive
San Jose, CA 95131-1807

MAR 1 1 1998

Re: K974360
Trade Name: Multitest CD3/CD8/CD45/CD4
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 requirements, 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

Attachment A

Indications for Use Statement

Device Name: **MultiTEST CD3/CD8/CD45/CD4**

Indications For Use:

- For the FACS® family of flow cytometers equipped with a blue (488-nm) and a red diode (635-nm) laser.
- A monoclonal antibody reagent for identification and enumeration of mature human T lymphocyte subsets in human peripheral blood.
- For use with erythrocyte lysed whole blood.
- To characterize and monitor forms of autoimmune diseases, such as lupus.
- To characterize and monitor congenital or acquired immunodeficiencies, such as SCID or AIDS.
- For in vitro diagnostic use.

Peter E Mahmoudi

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

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

(Optional Format 1-2-96)