K971205

Attachment F

Summary of Safety and Effectiveness

DEC - 1 1997

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

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

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Director, Regulatory Affairs - Corporate
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Summary date: March 31, 1997

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

Name: Becton Dickinson TriTEST™ reagent CD4 FITC/CD8 PE/CD3 PerCP; TruCount™ Absolute Count Tubes

Classification: Class II

Predicate Device (21 CFR 807.92(a)(3))
The BDIS TriTEST™ CD4 FITC/CD8 PE/CD3 PerCP reagent with TruCount Absolute Count Tubes is substantially equivalent to FACSCount (cleared to market under K933486).

Description of the Device (21 CFR 807.92(a)(4))
The BDIS TriTEST CD4 fluorescein isothiocyanate (FITC)/CD8 phycoerythrin (PE)/CD3 peridinin chlorophyll protein (PerCP) reagent is a three-color, direct immunofluorescence reagent. When used with TruCount Absolute Count Tubes it is used for identifying and enumerating absolute counts of T lymphocytes (CD3+), helper/inducer T lymphocytes (CD3+CD4+) and suppressor/cytotoxic T lymphocytes (CD3+CD8+) in erythrocyte-lysed whole blood (LWB). The Becton Dickinson TriTEST/TruCount system for immunophenotyping consists of a flow cytometer (either from BDIS or from another manufacturer), conjugated monoclonal reagent (TriTEST CD4 FITC/CD8 PE/CD3 PerCP) and TruCount Absolute Count Tubes.

The process to obtain T lymphocyte subset absolute counts includes: 1) obtaining a whole blood sample, 2) adding a precise volume of whole blood directly to the Absolute Count Tube, 3) cell-surface antigen staining with three-color monoclonal antibody reagents, 4) erythrocyte lysis, and 5) flow cytometric acquisition and analysis of list mode data. Analysis for absolute counts requires that the bead region be identified and the events in this region counted. The proportion of reagent positive events to bead events (P) is computed. The absolute count is P x (beads/pellet)/(volume of blood sample).

Summary of Safety and Effectiveness

When monoclonal antibody reagents are added to human whole blood, the fluorochrome-labeled antibodies bind specifically to antigens on the surface of leucocytes, thus identifying lymphocyte populations. The patient blood sample is added to the counting bead pellet and is treated with fluorochrome-labeled antibodies and the erythrocytes are lysed with FACS® Lysing Solution. The flow cytometer is set up so that cell populations for most samples occupy approximately the same region of fluorescence space. The sample is then introduced into the flow cytometer and the stained cells and beads fluoresce when excited by a laser beam.

The three-color reagent permits identification of T lymphocyte subsets using fluorescence gating instead of forward scatter gating. This three-color reagent allows direct gating on the CD3+ population using a combination of fluorescence and side scatter parameters. By gating on the CD3+ population, a maximum number of T lymphocytes may be captured in the gate.

Intended Use (21 CFR 807.92(a)(5))
For in vitro diagnostic use to identify and enumerate absolute counts of T lymphocyte (CD3+), helper/inducer T lymphocyte (CD3+CD4+) and suppressor/cytotoxic T lymphocyte (CD3+CD8+) subsets in blood.

Indications for Use

- For use with any flow cytometer equipped with a 488 nm laser and capable of detection in the ranges: 515-545 nm, 562-607 nm, and >650 nm
- For use with erythrocyte lysed whole blood
- For in vitro diagnostic use
- To identify and enumerate absolute counts of CD3+ and CD3+CD4+ and CD3+CD8+ lymphocytes
- To characterize and monitor some forms of immunodeficiency, such as in HIV infected individuals
- To characterize and monitor some forms of autoimmune diseases

Clinical Utility
The determination of T lymphocyte (CD3+), helper/inducer T lymphocyte (CD3+CD4+) and suppressor/cytotoxic T lymphocyte (CD3+CD8+) has been found useful in monitoring some forms of immunodeficiency and autoimmune disease.

Comparison to Predicate Device (21 CFR 807.92(a)(6))
The TriTEST/TRUCOUNT system (for absolute counts) is substantially equivalent to the FACSCount system for CD3+, CD3+CD4+ and for CD3+CD8+, (cleared to market under K933486). Both the TriTEST reagent with TRUCOUNT tubes and the predicate device yield equivalent results for the same analytes, and both are intended for use as an in vitro diagnostic test using a flow cytometer-based instrument and recommended computer hardware and software. Results demonstrate that the products yield essentially equivalent performance characteristics.

Summary of Safety and Effectiveness

Performance Data (21 CFR 807.92(b)(2))
Performance of the product was established by testing at Cleveland Clinic, Johns Hopkins Hospital, Institute of Tropical Medicine, University of North Carolina Hospital, and at Becton Dickinson Immunocytometry Systems laboratories in San Jose, California.

Several studies were performed:

- Accuracy data demonstrated the TriTEST/TRUCOUNT product's equivalence to FACSCount.

- A stability study was conducted to assess the time effect relating to age of blood (time-from-draw) and the time effect relating to the age of the stain (time-from-sample preparation), as well as the combined effect of both. Results indicate that for the calculation of absolute counts, blood specimen should be stained within 24 hours of draw, and analysis of the stained samples should occur within 24 hours or alternatively, the blood specimen can be stained within 48 hours of draw and analyzed within 6 hours.

- Within-specimen reproducibility was performed at BDIS; 10 replicates from 1 high, 1 medium, and 1 low were assessed. Within-specimen reproducibility was also performed at 3 clinical sites; 3 aliquots from each donor were assessed. Results demonstrated acceptable within-sample reproducibility.

- Linearity was determined using blood samples from 3 normal donors diluted to 5 concentrations, ranging from 16,700 to 200 lymphocytes/μL and from 31,000 to 2,500 WBC/μL. Results indicate a linear response over this range.

- Cross reactivity of these clones is reported in the literature. Conjugation and product formulation have not changed their specificity.

- Results from a cross platform reproducibility study for determining absolute counts using TriTEST CD4 FITC/CD8 PE/CD3 PerCP reagent with TRUCOUNT Absolute Count Tubes indicated a small (<20%) non-zero bias, but good correlation between results on a Becton Dickinson flow cytometer versus a Coulter. Therefore, users will be advised that they must validate performance characteristics for absolute counts, as required under CLIA regulations (42 CFR 493.1202 and 493.1213).

Performance Data - Conclusions (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.

DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
2098 Gaither Road
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Director, Regulatory Affairs
BECTON DICKINSON IMMUNOCYTOMETRY SYSTEMS
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San Jose, CA 95131-1807

DEC - 1 1997

Re: K971205
Trade Name: Becton Dickinson TriTEST Reagent CD4 FITC/CD8 PE/CD 3 PerCP; TruCOUNT Absolute Count Tubes
Regulatory Class: II
Product Code: GKZ, 81
Dated: March 31, 1997
Received: April 1, 1997

Dear Ms. Longwell:

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

510(k) Number (if known): K971205

Device Name: _____

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Indications For Use:

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Peter E. Maloney

(Division Sign-Off)
Division of Clinical Laboratory Devices
510(k) Number K971205

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

(Optional Format 1-2-96)