K970836

Attachment D

Summary of Safety & Effectiveness

AUG 26 1997

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

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

Contact: Anna Longwell, Esq.
Director, Regulatory Affairs – Corporate
(408) 954-2254

Summary Date: February 24, 1997

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

Name: TRUCOUNT™ Absolute Count Tubes

TRUCOUNT™ Counting Control Beads

Classification: Accessories to a Class II Product, Lymphocyte immunophenotyping reagent

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

Lymphocyte immunophenotyping reagents, when used for absolute counts are substantially equivalent to Simultest™ reagents, cleared in the Simultest IMK-Lymphocyte Kit, (K913192), plus ADCC, or, in the case of TriTEST™ reagents CD3/CD4/CD45 and CD3/CD8/CD45, to FACSCount, K933486. The absolute count application is the subject of current lymphocyte immunophenotyping reagent submissions.

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

TRUCOUNT Absolute Count Tubes are fluorescent particles supplied as a pellet in a tube. The pellet contains a known number of beads. A blood sample of known volume is added to the tube. Then the appropriate reagent is added to the mixture. By comparing the number of positive cell events to the number of bead events in the flow cytometry data output, positive cells per unit volume of blood sample can be computed.

TRUCOUNT Counting Control Beads are fluorescent particles supplied as suspensions in three bead concentrations, High, Medium and Low. The fluorescence of these beads is similar to that of the Absolute Count Tube in FL1 and FL3, but is different in FL2, so that both beads may be run in the same sample, and distinguished from one another. Control beads are added to samples of normal blood prepared with TriTEST reagents and Absolute Count Tubes. The Control Bead count is obtained by comparison to the count of the Absolute Count Tubes. These experimental counts are compared to the expected count on the Control Bead label, to check the accuracy of pipetting.

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

TRUCOUNT Absolute Count Tubes are intended for use as an accessory to TriTEST in vitro diagnostics, such as that described in K965053 (CD3/CD4/CD45), to allow computation of positive cells per known volume of blood, using flow cytometry.

The TRUCOUNT Counting Control Beads are provided in three levels, and are intended to provide a means to check the reproducibility and accuracy of volumetric pipetting of blood samples. They are an accessory to TriTEST reagents, when used with TRUCOUNT Absolute Count Tubes to obtain absolute counts of positive cells using flow cytometry.

Indications for Use

- For erythrocyte lysed whole blood
- For use with FACS Loader
- For use with IVD immunophenotyping reagents
- For use on flow cytometers with designated detection ranges

Clinical Utility

The determination of absolute counts of subtypes of lymphocytes has been found useful in monitoring some forms of immunodeficiency and autoimmune disease.

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

Use of the TRUCOUNT Absolute Count Tubes with each of the TriTEST reagents was compared to either FACSCount, K933486 (for CD3/CD4/CD45 and CD3/CD8/CD45), or to the appropriate vial of IMK-Lymphocyte, K913192, plus ADCC. Substantial equivalence of the beads when used with other flow cytometry reagents is included in the respective reagent submission (e.g., TriTEST CD3/CD4/CD45, K965053). Data for these comparisons is not included in this submission.

Use of the TRUCOUNT Counting Control Beads does not change the safety and effectiveness of the above assays.

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

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

- Stability of the Absolute Count Tube and Counting Control Bead was assessed and found to be acceptable to support a one year and six month shelf life, respectively.
- Accuracy and reproducibility of the Counting Control Beads was determined and found to be acceptable to support the ranges for acceptable performance cited in the Package Insert.
- Absolute Count Tubes were found to remain stable after the foil pouch is opened, as long as the pouch is stored closed at room temperature, and the desiccant remains blue.
- The Absolute Count Tubes and Counting Control Beads were seen to function as expected when used with the FACS Loader, as well as manually.

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

The results of the studies demonstrate that:

- Expiration dating claim for the TRUCOUNT Absolute Count Tube Product is one year.
- Expiration dating claim for the TRUCOUNT Counting Control Beads is six months.
- TRUCOUNT Absolute Count Tube and TRUCOUNT Counting Control Bead Product may be used with the FACS Loader.

The product does not change the substantial equivalence of the reagents it is used with, as demonstrated in the respective reagent submissions.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

Ms. Anna Longwell, Esq.
Director, Regulatory Affairs-Corporate
Becton Dickinson Immunocytometry Systems
2350 Qume Drive
San Jose, California 95131-1807

AUG 26 1997

Re: K970836/S2
Trade Name: Becton Dickinson TruCount™ Absolute Count Tubes and TruCount™ Counting Control Beads
Regulatory Class: II
Product Code: GKZ
Dated: June 5, 1997
Received: June 10, 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 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): K970836

Device Name: TruCount Absolute Count Tubes
TruCount Counting Control Beads

Indications For Use:

- For use with FACS Loader
- For use with *in vitro* diagnostic immunophenotyping reagents
- For use in erythrocyte lysed whole blood
- For use to obtain absolute counts by flow cytometry

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

[redacted]
(Division Sign-Off)
Division of Clinical Laboratory Devices
510(k) Number [redacted]

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

(Optional Format 1-2-96)