K082091

ReaMetrix
Accelerating Innovation

510(k) Summary

APR 15 2009

Submitter information

Submitter: Reametrix, Inc.
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Director
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Summary preparation date: December 5, 2008

Device names and classification

Trade name: Dry Tri T-STAT (CD3/CD4/CD8) reagent
Common name: CD3-PE-D649/CD4-A488/CD8-PE reagent with fluorescent counting beads
Device classification: The Dry Tri T-STAT (CD3/CD4/CD8) reagent is a Class II device (21 CFR 864.5220, Panel code: GKZ)

Predicate devices

Becton Dickinson TriTEST™ reagent CD4 FITC/CD8 PE /CD3 PerCP; TruCOUNT™ Absolute counting tubes (K971205)
Beckman Coulter CYTO-STAT® CD45-FITC/CD4-PE/CD8-ECD/CD3-PC5 tetraCHROME™ (K030408)

Device Description

The Dry Tri T-STAT (CD3/CD4/CD8) reagent contains Atto488 – labeled CD4 monoclonal antibody (clone RPA-T4); phycoerythrin(PE) – labeled CD8 monoclonal antibody (clone LT8); and PE – Dyomics649 – labeled CD3 monoclonal antibody (clone UCHT1) formulated with fluorescent counting beads and stabilizers. The conjugated antibodies and beads are dispensed into flow cytometer compatible plastic tubes and dried. The material in each tube is used to process a single sample.
The Dry Tri T-STAT (CD3/CD4/CD8) reagent, three color immunofluorescence stain, labels, identifies, and enumerates helper/inducer (CD3+CD4+) and cytotoxic/suppressor (CD3+CD8+) T lymphocytes. Combined with a precise number of fluorescent counting beads, in each tube, the reagent provides absolute CD4+ and CD8+ T-Cell counts on a single platform.

Intended Use

The Dry Tri T-STAT (CD3/CD4/CD8) reagent is a three color immuno-fluorescence stain for the labeling, identification, and enumeration of helper/inducer (CD3+CD4+) and cytotoxic/suppressor (CD3+CD8+) T lymphocytes combined with a precise number of fluorescent counting beads for absolute CD4+ and CD8+ T-Cell counts. This reagent is intended to be used in a "no wash" protocol for flow cytometric analysis of erythrocyte-lysed human whole blood.

Technological Characteristics

The Dry Tri T-STAT (CD3/CD4/CD8) reagent, like the predicate devices, contains fluorescently labeled antibodies and fluorescent counting beads that are used to stain specific T-cell populations. These stained cells can be analyzed on any flow cytometer equipped with a 488nm laser, scattering detection, and capable of fluorescence detection in the ranges 515-545nm, 562-607nm, and >650nm.
Fluorescence from the CD4-A488, CD8-PE, and CD3-PE-D649 antibody conjugates can be detected in each of the three wavelength ranges when specifically bound to the cells. The counting beads can be used to determine the volume of sample analyzed on the flow cytometer when a precise volume of blood is dispensed into the tube containing the conjugates and a known number of beads. This allows the single platform determination of the absolute CD4+ and CD8+ T-cell counts.

Performance Characteristics

1. Precision/Reproducibility
   Within run reproducibility was determined by performing 10 replicates of a high, medium, and low count samples. The results were found to be acceptable with average %CV better than 10%.

2. Linearity
   The linearity was determined over the reportable ranges for CD4+ (65-1500 cells/µl) and CD8+ (50-1500 cells/µl) T-cells. The linearity was found to be acceptable with correlation coefficients greater than 0.99.

3. Sample stability
   Sample stability was assessed at 24 hour intervals from the time of phlebotomy. Sample stability with respect to absolute CD4+ and CD8+ T-cell concentrations were acceptable when analyzed 24 hours post draw. If samples were processed at the time of phlebotomy then the counts was found to be stable for 7 days.

4. Cross reactivity
   The monoclonal antibodies used in the Dry Tri T-STAT (CD3/CD4/CD8) reagent were assigned these specificities at the International Workshops on Human Leukocyte Differentiation Antigens. Conjugation has not changed their specificities.

5. Correlation to predicate devices
   The Dry Tri T-STAT (CD3/CD4/CD8) reagent was compared to the predicate devices at four different sites (291 samples). The correlation of absolute CD4+ & CD8+ T-cell counts were R^2=0.99, 0.93, 0.91, & 0.99 and R^2=0.96, 0.91, & 0.96, respectively.

Conclusion

The information presented in this pre-market notification for the Dry Tri T-STAT (CD3/CD4/CD8) reagent demonstrates substantial equivalence to the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

RealMetrix, Inc.
c/o Mr. Steve Kunitake
Director
1585 Industrial Road
San Carlos, CA 94070

APR 15 2009

Re: k082091
Trade/Device Name: Dry Tri T- STAT (CD3/CD4/CD8) reagent
Regulation Number: 21 CFR 864.5220
Regulation Name: Automated Differential Cell Counter
Regulatory Class: II
Product Code: GKZ
Dated: April 1, 2009
Received: April 6, 2009

Dear Mr. Kunitake:

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.

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 advice for your device on the labeling regulation, please contact the Office of In Vitro Diagnostic Device Evaluation and Safety at 240- 276-0450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For question regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR), please contact the Division of Surveillance Systems at 240-276-3464. You many 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 (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Maria M. Chan, 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

510(k) Number (if known): K082091

Device Name: Dry Tri T-STAT (CD3/CD4/CD8) reagent

Indications For Use:

The Dry Tri T-STAT (CD3/CD4/CD8) reagent, intended for in vitro diagnostic use, is a three color immunofluorescence stain for the labeling, identification, and enumeration of helper/inducer (CD3+CD4+) and cytotoxic/suppressor (CD3+CD8+) T lymphocytes combined with a precise number of fluorescent counting beads to provide absolute CD4+ and CD8+ T-Cell counts on a single platform. This reagent is intended to be used for flow cytometric analysis of erythrocyte-lysed human whole blood. The Tri T-STAT Reagent can be used to monitor forms of immunodeficiency.

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-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

Division Sign-Off

Office of In Vitro Diagnostic Device Evaluation and Safety

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