K960887

510(k) Summary

MAY 17 1996

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Date Summary Prepared:	December 21, 1995
Device Name:	Mouse Anti-Human T-cell, CD4/FITC, MT310 + Mouse Anti-Human T-cell, CD8/RPE,DK25
Device Classification:	Class II according to 21 CFR 864.5220, on the basis that monoclonal antibodies are accessories for automated differential cell counters.
Panel:	This device classification is under the Hematology and Pathology devices panel, Division of Clinical Laboratory Devices.
Product Code:	GKZ
Predicate Device(s):	CytoStat/Coulter Clone T8-RD1/T4-FITC
Device Description:	Purified mouse anti-human CD4, CloneMT310, conjugated with fluorescein isothiocyanate, isomer 1 (FITC) + purified mouse anti-human CD8, Clone DK25, conjugated with R-phycoerythrin, present in 0.05M Tris-HCl buffer, pH 7.2, 15 mM NaN_3, 0.1M NaCl, stabilized with 1% carrier protein Subpopulations of lymphocytes may be stained with fluorochrome-conjugated antibody and evaluated in peripheral blood specimens when contaminating red blood cells (RBC's) are lysed prior to flow cytometric analysis. A subpopulation of WBC's are selected for assessment based upon cell morphology.
Intended Use:	For *In Vitro* Diagnostic Use Mouse Anti-Human T-cell, CD4/FITC, MT310 + Mouse Anti-Human T-cell, CD8/RPE,DK25 (DAKO CD4/CD8) has been developed for use in flow cytometry for the analysis of T-helper/inducer cells and T-cytotoxic/suppressor cells. This reagent allows simultaneous detection and quantification of helper/inducer T-cells (CD4+ cells) and cytotoxic/suppressor T-cells (CD8+ cells) in peripheral blood of normal and pathological conditions such as immunodeficiency disorders. It is one component of the suggested monoclonal antibody (MAb) combinations for routine immunophenotyping of lymphocytes in peripheral blood using flow cytometry.
Comparison of Technological Characteristics	Performance characteristics have been established by clinical evaluation of compared to the individual single reagent predicate devices that quantitatively measure $CD4^+$ and $CD8^+$ T-cells that have been previously cleared by FDA (CytoStat/CoulterClone T8-RD-1/T4-FITC). When flow cytometric tests of peripheral blood samples obtained from apparently healthy adults were completed, correlation of CytoStat/CoulterClone T8-RD-1/T4-FITC with DAKO CD4/CD8 approached a direct 1 : 1 comparison for measurement of CD4+ cells. Correlation of CytoStat/CoulterClone T8-RD-1/T4-FITC with DAKO

CD4/CD8 approached a direct 1 : 1 comparison for measurement of CD8+ cells. Data for the measurement of CD4+ T-cells by DAKO CD4/CD8 reagent compared to CytoStat/CoulterClone T8-RD-1/T4-FITC on peripheral blood samples obtained from apparently healthy adults as well as ill patients gave a correlation greater than 0.98 using the whole blood method for flow cytometry. Data for the measurement of CD8+ T-cells by DAKO CD4/CD8 reagent compared to CytoStat/CoulterClone T8-RD-1/T4-FITC gave a correlation greater than 0.98 using the whole blood method for flow cytometry.

The CD4 antibody clone, MT310, was clustered at the Second Leukocyte Typing Workshop,Boston , 1984. The CD8 antibody clone, DK25, was clustered at the Third Leukocyte Typing Workshop,Oxford, England, 1986 under another clone designation.

Linearity testing of DAKO CD4/FITC using CEM cells gave the following linear equation:

$$y = 4.26\% + 0.93x;\ r = 0.999$$

Linearity testing of DAKO CD8/PE using JM cells gave the following linear equation:

$$y = 0.06\% + 1.01x;\ r = 0.999$$

In addition, reproducibility of DAKO reagents using replicates (from peripheral blood) run on two different flow cytometers was measured at three concentrations of each antigen. Cross-reactivity of CD4/CD8 with peripheral blood cells (red blood cells, monocytes, granulocytes, lymphocytes, and platelets) was measured.

Conclusions:

Results of the above testing as well as the information provided by the Second and Third Leukocyte Typing Workshops indicate that the CD4/CD8 reagent performs as well as CytoStat/CoulterClone T8-RD-1/T4-FITC in the detection and enumeration of $CD4^+$ and $CD8^+$ lymphocytes using flow cytometry. Safety of the DAKO CD4/CD8 reagent and its predicate device is high as are all reagents used for in vitro testing.