Attachment E

Summary of Safety and Effectiveness

K963963

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

Submitter: Becton Dickinson Immunocytometry Systems
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DEC 12 1996

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

Name: MultiSET™ software

Classification: Class II

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

MultiSET software for automated flow cytometric analysis of TriTEST reagents is substantially equivalent to the predicate software, CELLQuest™, which was described in 510(k) K946055.

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

Becton Dickinson MultiSET software is a three-color, direct immunofluorescence method for identifying and enumerating percentages of lymphocyte subsets in erythrocyte-lysed whole blood. The software is an accessory to reagent products which use CD45 gating for immunophenotyping by flow cytometry.

Both the manual CELLQuest software and the automated MultiSET software rely on a lymphocyte gate drawn for the $CD45^+$ leucocytes with low side scatter. Lymphocyte subsets as a percent of total lymphocytes are then identified as a proportion of events included in the lymphocyte gate.

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

MultiSET is an accessory software to in vitro diagnostic reagents employing CD45 gating for identification and enumeration of lymphocyte subsets in human peripheral blood.

Clinical Utility

The determination of lymphocyte subsets have been found useful in monitoring some forms of immunodeficiency and autoimmune disease.

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

The MultiSET automated software is substantially equivalent to the CELLQuest software in that they share the same intended uses and similar methodologies. Results demonstrate that the products yield essentially equivalent performance. The products differ in that MultiSET software automates the steps used to determine analysis gates to identify the lymphocyte populations.

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.

Accuracy was determined by comparison of results from the automated MultiSET software with results from the predicate manual software. Lysed whole blood samples from 41 donors, including 17 normals and 24 abnormals, were analyzed by the automated and manual softwares. Accuracy data demonstrated that MultiSET software provides equivalent results to the manual CELLQuest software.

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

The results of the evaluation studies demonstrate that the device is as safe and effective as the predicate device.