



K964053

NOV - 1 1996

Re: HemoCue GlucoTrol
510(k) Notification

SMDA Summary

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92

Representative Labels, Labeling and Advertisements

Included in this submission are samples or copies of the vial labels, box labeling, product description/instructions for use, and assay values for GlucoTrol, which have been prepared in accordance with the FDA labeling requirements of 21 CFR 809.10.

Substantial equivalence of GlucoTrol control to devices already on the market

For the purposes of demonstrating substantial equivalency, HemoCue GlucoTrol control is compared to the HemoCue Whole Blood Control, manufactured for HemoCue by Streck Laboratories, Inc., 14306 Industrial Road, Omaha, Nebraska, 68144. Product descriptions, intended use and assay values for this product are provided for comparison.

These two products are similar in matrix, chemical composition, technological characteristics, intended use, and packaging specifications.

Information and Data Supportive of Substantial Equivalency Claim

In addition to the product descriptions and intended use insert sheets referenced above, further evidence is provided which offers supporting data relative to the product shelf life, open vial stability (room temp. and 2-8°C), compatibility and non-interference with the intended analyzer, and comparable precision and accuracy as compared to the Streck Laboratories manufactured product. Test data include:

1. An open vial and closed vial glucose stability study.
2. A day-to-day precision study.
3. A precision study of five (5) levels of HemoCue GlucoTrol as compared to three (3) levels of HemoCue Whole Blood Control (manufactured by Streck Laboratories), measured on five different HemoCue B-Glucose analyzers, in replicates of six (6).

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