DIRECT
SOLUTIONS

OCT 16 1996

K963908

Re: HemoCue HemoLin
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 HemoLin, which have been prepared in accordance with the FDA labeling requirements of 21 CFR 809.10.

Substantial equivalence of HemoLin control to devices already on the market

For the purposes of demonstrating substantial equivalency, HemoCue HemoLin 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 attached 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 enclosed which provides 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. Six shelf life validation time studies, at 2-8°C and 25°C, over periods ranging from 0 to 876 days, incorporating a variety of production lots.

2. A precision study of five (5) levels of HemoCue HemoLin as compared to three (3) levels of HemoCue Whole Blood Control (manufactured by Streck Laboratories), measured on three (3) different HemoCue B-Hemoglobin analyzers, in replicates of 10.

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