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I. SUMMARY OF SAFETY AND EFFECTIVENESS

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DEVICE NAME: INCSTAR HSV I/II IgG "fast" ELISA Kit

CLASSIFICATION: Herpes simplex virus serological reagents
21 CFR 866.3305
Class III

APPLICANT: INCSTAR Corporation
1990 Industrial Boulevard
Stillwater, Minnesota 55082-0285

INTENDED USE:

The INCSTAR Herpes Simplex Virus I/II IgG "fast" ELISA kit contains instructions and materials for the qualitative and/or semi-quantitative detection of IgG antibodies to herpes simplex virus type 1 and/or type 2 in human serum by indirect enzyme-linked immunosorbent assay (ELISA) technique. When performed according to instructions, the INCSTAR Herpes Simplex Virus I/II IgG "fast" ELISA test is of value in the determination of immunological response to infection with HSV. The evaluation of paired sera, acute and convalescent, by demonstrating seroconversion or a significant rise in antibody can aid in the diagnosis of primary infection with herpes simplex virus.

DEVICE DESCRIPTION:

The method for the determination of specific anti-HSV type 1 and/or type 2 IgG utilizes the enzyme-linked immunosorbent assay (ELISA) technique. Polystyrene microtiter wells are coated with purified HSV type 1 and type 2 antigens. Diluted patient serum is incubated with the purified HSV antigens bound to the solid surface of the microtiter well. The HSV type 1 and/or type 2 IgG antibodies present in a patient's serum will be captured by the solid phase. After washing, affinity purified polyclonal goat anti-human IgG (Fc) antibodies conjugated to horseradish peroxidase are added to the well. After this incubation, chromogen containing tetramethylbenzidine is added. Enzyme action on the chromogen results in a color reaction. The color can be detected with a photometer at a wavelength of 450 nm. The measured enzyme activity is

directly proportional to the concentration of specific anti-HSV IgG bound to the solid phase.

SAFETY AND EFFECTIVENESS:

The INCSTAR HSV I/II IgG "fast" ELISA Kit is substantially equivalent (SE) to the Herpes 1 IgG Clin-ELISA kit, 510(k) No. K852782 in combination with the Herpes 2 IgG Clin-ELISA kit, 510(k) No. K852781 which have been cleared by the FDA and are currently in U.S. commercial distribution.

In clinical performance studies, 305 serum samples represented by 305 individuals were tested with the INCSTAR HSV I/II IgG "fast" ELISA Kit and results were compared to those results generated from the Herpes 1 IgG Clin-ELISA and Herpes 2 IgG Clin-ELISA kits. The samples utilized represent a mixed population of healthy individuals, transplant patients, and patients with various illnesses. Upon completion of assay correlation, the results (using 95% confidence intervals) demonstrated a relative sensitivity of 94% to 99%, a relative specificity of 85% to 95%, and an overall agreement of 90% to 100%.

Further resolution of discrepant results by a commercial HSV IgG IFA demonstrated that of the 13 samples positive by the INCSTAR HSV I/II IgG "fast" assay but negative by the reference ELISA assays, 11 were positive by IFA. Of the 4 samples negative by the INCSTAR HSV I/II IgG "fast" assay but positive by the reference ELISA assays, 1 was negative by IFA.

Prevalence, cross-reactivity, interference, linearity and precision studies have been conducted and are summarized in the INCSTAR HSV I/II IgG "fast" ELISA Kit package insert. (See Section VII.A.1. Package Insert).