DEC 16 1996 K963096

I. SUMMARY OF SAFETY AND EFFECTIVENESS

DEVICE NAME: INCSTAR Toxoplasma IgG ELISA Kit

CLASSIFICATION: *Toxoplasma gondii* Serological Reagents
21 CFR 866.3780
Class II (Performance Standards)

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

INTENDED USE:

The INCSTAR Toxoplasma IgG ELISA kit contains instructions and materials for qualitative and/or semi-quantitative detection of IgG antibodies to *Toxoplasma gondii* in human serum by indirect enzyme-linked immunosorbent assay (ELISA) technique. When performed according to instructions, the Toxoplasma IgG ELISA is of value in the determination of immunological response to infection with *Toxoplasma gondii.* The evaluation of paired sera, acute and convalescent, by demonstrating seroconversion or a significant rise in antibody can aid in the diagnosis of primary or reactivated infection with *Toxoplasma gondii.* This product is not FDA cleared for use in testing (i.e., screening) blood or plasma donors.

I. SUMMARY OF SAFETY AND EFFECTIVENESS (continued)

DEVICE DESCRIPTION:

The method for the determination of specific anti-*Toxoplasma* IgG utilizes the enzyme-linked immunosorbent assay (ELISA) technique. Polystyrene microtiter wells are coated with purified *Toxoplasma gondii* antigen. Diluted patient serum is incubated with the purified antigen bound to the solid surface of a microtiter well. The *Toxoplasma* 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 dual wavelength of 450 nm / 630 nm. The measured enzyme activity is directly proportional to the concentration of specific anti-*Toxoplasma* IgG bound to the solid phase.

SAFETY AND EFFECTIVENESS:

The INCSTAR Toxoplasma IgG ELISA Kit is substantially equivalent (SE) to the Gull Toxoplasma IgG ELISA test, 510(k) No. K915891, which has been cleared by the FDA and is currently in U.S. commercial distribution.

In clinical performance studies, 300 serum samples represented by 269 individuals were tested with the INCSTAR Toxoplasma IgG Kit and results were compared to those results generated from the Gull Toxoplasma IgG ELISA kit. The samples utilized represent a mixed population of infants, transplant patients, immunocompromised hosts, pregnant women being screened for toxoplasmosis, and patients having various other illnesses. Upon completion of assay correlation, the results (using 95% confidence intervals) demonstrated relative sensitivity of 98% to 100% and relative specificity of 92% to 99%. In addition, the assay displayed an overall agreement of 96% to 99%.

I. SUMMARY OF SAFETY AND EFFECTIVENESS (continued)

Correlation, prevalence, cross-reactivity, interference, linearity and precision studies have been conducted and are summarized in the INCSTAR Toxoplasma IgG Kit package insert.