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I. SUMMARY OF SAFETY AND EFFECTIVENESS

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DEVICE NAME: INCSTAR Rubella IgG ELISA Kit

CLASSIFICATION: Rubella virus serological reagents
Section 21 CFR 866.3510
Class III

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

INTENDED USE:

The INCSTAR Rubella IgG ELISA Kit contains instructions and materials for the qualitative and/or semi-quantitative detection of IgG antibodies to rubella in human serum by indirect enzyme-linked immunosorbent assay (ELISA) technique. When performed according to instructions, the Rubella IgG ELISA test is of value in the determination of rubella immunological status. The evaluation of paired sera, acute and convalescent, by demonstrating seroconversion or a significant rise in antibody can aid in the diagnosis of current or recent infection with rubella.

DEVICE DESCRIPTION:

The INCSTAR Rubella IgG ELISA test kit utilizes the ELISA technique for the detection of rubella IgG antibodies. Diluted patient serum is incubated with purified rubella antigen bound to the solid surface of a microtiter well. If IgG antibodies to rubella are present in the patient's serum, antigen-antibody complexes are formed. These complexes bind with horseradish peroxidase labeled antihuman IgG which react with the addition of chromogen, resulting in color development. The absorbance of the solution, measured at 450 nm, is directly proportional to the concentration of IgG antibodies to rubella antigen present in the reaction solution.

I. SUMMARY OF SAFETY AND EFFECTIVENESS (continued)

SAFETY AND EFFECTIVENESS:

The INCSTAR Rubella IgG ELISA Kit is substantially equivalent (SE) to the Rubella IgG Clin-ELISA Kit, 510(k) No. K860145, which has been cleared by the FDA and is currently in U.S. commercial distribution.

In clinical performance studies, 497 serum samples represented by 497 individuals were tested with the INCSTAR Rubella IgG ELISA Kit and results were compared to those results generated from the Rubella IgG Clin-ELISA kit. The samples utilized represent a mixed population of clinical patients (non-rubella disease related), newborns, employee/student screenings, and pregnant women. Upon completion of assay correlation, the results (using 95% confidence intervals) demonstrated a relative sensitivity of 91% to 100% and a relative specificity of 97% to 100%. In addition, the assay displayed an overall agreement of 96% to 99%.

Further resolution of discrepant results by a commercial Rubella IgG EIA (Abbott Rubazyme EIA, 510(k) No. K885297) demonstrated that of the 5 samples positive by the INCSTAR Rubella IgG assay but negative by the reference ELISA assay, 4 were positive by the Rubazyme assay. Of the 7 samples negative by the INCSTAR Rubella IgG assay but positive by the reference ELISA assay, 4 were negative by the Rubazyme assay.

Prevalency, cross-reactivity, interference, linearity and precision studies have been conducted and are summarized in the INCSTAR Rubella IgG Kit package insert. (See Section VII.A.1. Package Insert)