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510(k) Summary of Safety and Effectiveness

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.

Ventana Medical Systems, Inc. developed the Ventana Anti-S100 antibody for use on the Ventana ES automated immunohistochemistry system. Ventana Anti-S100 is substantially equivalent to other marketed immunohistochemical stains used in the identification of cells of normal and abnormal lineage as an aid in diagnosis of anaplastic tumors. Epithelial Membrane Antigen (EMA) is such a stain.

Antibody

Ventana Medical Systems' Anti-S100 (rabbit polyclonal) contains rabbit antiserum directed against an epitope found on S100 protein. S100 used for immunization was purified by ammonium sulphate fractionation, DEAE-Sephadex chromatography and gel filtration on Sephadex G100. The antiserum was obtained from rabbits after repeated injections of S100 protein complexed to methylated bovine serum albumin in complete Freund's adjuvant. To determine if positive staining was a consequence of the S100 antiserum-S100 antigen interaction, 50 μ g of S100 protein was mixed with a 1/200 dilution of S100 antiserum prior to immunostaining. Pre-absorption resulted in complete loss of staining of tissue sections.

Comparative Study

Supporting data for the equivalence statement is shown by the following study.

Paraffin embedded preparations from normal and pathologic samples were tested using the Ventana Anti-S100. Samples were obtained from excess tissues obtained for reasons other than the present study. Pathologic tissues evaluated for staining included leiomyosarcomas, squamous cell carcinomas, breast carcinomas, carcinoid tumors and melanomas. Slides were processed on the Ventana ES Automated Slide Stainer and prepared for examination, then evaluated for specific staining intensity and background staining.

Results

Sensitivity of Ventana Anti-S100 was shown by the appropriate staining of nerve cells in normal tissues tested and staining of 80% of the melanoma tissues tested. This data compares favorably to published literature.

Inter-run reproducibility was determined based on samples of the same tissue on 16 different instrument runs. Staining intensity and pattern of staining was similar in all tissue slides evaluated. Intra-run reproducibility was determined based on ten samples of the same tissue within one run. The staining intensity and pattern of staining in the ten slides was similar in all slides.