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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-Vimentin Primary Antibody for use on the Ventana ES automated immunohistochemistry system. Ventana Anti-Vimentin (clone VIM 3B4) is substantially equivalent to other marketed immunohistochemical stains used in the identification of cells of normal and abnormal lineage as an aid in the diagnosis of anaplastic tumors.

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 Ventana Anti-Vimentin. Samples were obtained from excess tissues obtained for reasons other than the present study. Pathologic tissues evaluated for staining included breast carcinomas, melanomas, squamous cell carcinomas and leiomyosarcomas. Slides were processed on the Ventana ES Automated Slide Stainer and prepared for examination, then evaluated on a blind basis for specific staining intensity and background staining.

Results

Sensitivity of the antibodies was shown by appropriate staining of cells of mesenchymal origin and agreement with reported literature (Barwick, K.W. Intermediate Filaments and Keratin in Atlas of Diagnostic Immunohistopathology. Ed. L.D. True. 1990. J.B. Lippincott Co., Philadelphia. Azumi N. and H. Battifora Am J. Clin Pathol. 1987;Vol 88, pg 286-296.). In the Ventana study, 20 of 20 melanomas and 8 of 8 sarcomas stained positively compared to 16 of 18 melanomas and 17 of 20 sarcomas reported by Azumi and Battifora. Adenocarcinoma (0/9), Squamous cell carcinoma (0/10), and Carcinoid (0/9) compared favorably to positive test results reported by Azumi and Battifora, 15/147, 1/7, and 1/10, respectively.

Inter-run reproducibility, based on samples of the same tissue on 16 different instrument runs. Staining was equivalent for all slides. Intra-run reproducibility, based on 10 samples of the same tissue within one run. Staining was equivalent for all slides.