

K960381

APR 29 1996

SUMMARY OF SAFETY AND EFFECTIVENESS

The 510(k) premarket notification for the Automatic Filter Selection Option for the MAM-CH22S mammography system describes a modification of the legally marketed mammography system (K941353/S1) by the addition of the optional filter assembly (including molybdenum and rhodium filters) and its automatic mode of operation.

With regards to effectiveness, the intended use and the indications of use of the MAM-CH22S with the Automatic Filter Selection Option are identical to those of the MAM-CH22S. With the Automatic Filter Selection mode, dense or thick breasts can be imaged with improved contrast and/or less radiation dose when the mammography system automatically selects the rhodium filter.

With regards to safety, the MAM-CH22S mammography system with the Automatic Filter Selection Option was designed to comply with International Standard IEC (International Electrotechnical Commission) 601-1, Medical Electrical Equipment, Part 1: General Requirements For Safety. The modification was analyzed and preventive measures were taken.

Based on this analysis, to the best of our judgment, the addition of the Automatic Filter Selection Option modification to the MAM-CH22S mammography system, does not add a significant risk that can cause a safety hazard.

Based on the above, it is Elscint's opinion that the MAM-CH22S mammography system with the Automatic Filter Selection Option, is substantially equivalent in safety and effectiveness to the legally marketed device, MAM-CH22S.