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## Summary of Safety and Effectiveness

QuantEM™ package is a renal analysis package for Tc-99m MAG3 renal images. The QuantEM™ method was developed at Emory University, Atlanta, GA for calculating the clearance of Tc-99m MAG3. It provides a comprehensive package consisting of processing and protocols to aid the technologist and physician in the performance and interpretation of Tc99m MAG3 renograms.

The QuantEM™ package is implemented on the Apex XPert workstation of the Varicam gamma camera (K953801).

The effectiveness of the QuantEM™ package, implemented on the Apex XPert, is equivalent to the effectiveness of the QuantEM™ package implemented on GE Starcam computers (K932957).

The addition of the QuantEM™ package does not effect the safety and effectiveness of all other functions performed by the Apex XPert workstation.

Precautions to avoid erroneous processing results were taken and the necessary validation and tests were made to ensure correct processing results of the QuantEM™ package.

Based on the above, it is Elscint's opinion that the XPert QuantEM™ package usage is substantially equivalent in safety and effectiveness to QuantEM™ package on General Electric nuclear medicine computers (K932957), and that the Apex XPert workstation equipped with the QuantEM™ package is substantially equivalent in safety and effectiveness to the previously marketed version of the Varicam's Apex XPert workstation (K953801).