APR 1 9 1996

ATTACHMENT I

Summary of Safety and Effectiveness

SUMMARY OF SAFETY AND EFFECTIVENESS

1.   General Information

Classification:	Class II Magnetic Resonance (MR) Imaging System
Common/Usual Name:	MRI System Option
Proprietary Name:	Phase Conjugate Symmetry Option for Outlook
Establishment Registration:	Picker Nordstar, Inc. P.O. Box 33 FIN-00511 Helsinki, Finland FDA Facility Registration #9680194
Performance Standards:	Not applicable

2.   Intended Uses

The Phase Conjugate Symmetry (PCS) Option reduces the acquistion time by approximately 40% without impacting the resolution. The indications for use are the same as for standard MR Imaging.

3.   Device Description

The Phase Conjugate Symmetry (PCS) Option is a software feature which reduces the acquistion time by reducing the number of phase encodings needed to create an image.

4.   Safety and Effectiveness

The safety specifications for static magnetic field, time varying magnetic field, SAR levels and acoustic noise established for the Outlook system (K945827) are unaffected by the Phase Conjugate Symmetry Option and therefore remain unchanged.

As shown in the chart below, the Phase Conjugate Symmetry Option for Outlook is identical with regards to image performance to the Phase Conjugate Symmetry

feature introduced by Picker International in the DVP Software Option 510(k) submission (K895151).

Parameter	Phase Conjugate Symmetry Option for Outlook	Predicate Device DVP Software (K895151)
General Use	Operator selectable, can be used with all sequences with the exception of when the phase image option is chosen.	Operator selectable, can be used with any 2DFT and 3DFT sequence with the exception of read conjugate symmetry sequences.
Reconstruction Algorithm	Same as predicate.	Symmetry properties of the Fourier transform used to synthesize uncollected data.
Acquistion Time	Same as predicate.	Reduced as compared to a "normal" acquistion.
SNR	Same as predicate.	Reduce in a mathmatically predictable manner.
Resolution	Same as predicate.	No Impact.
Intended Use	Same as MR	Same as MR