SUMMARY OF SAFETY AND EFFECTIVENESS

K962618

SEP - 4 1996

1. Device Name: Gyrex V-EP.

1.2 Classification Name: Magnetic Resonance Diagnostic Device

1.3 Submitter: Elscint, Inc., 505 Main St., Hackensack, NJ 07601

1.4 510(k) Number:_____.

2. Identification of Predicate Device: The predicate device is the Elscint Gyrex Privilege system (K954039).

3. Comparison to Predicate Device

The Gyrex V-EP is a modification of the Gyrex Privilege system that enables current owners of the Gyrex V-Dlx to upgrade to the Gyrex Privilege without having to replace their existing magnet. The differences between the Gyrex V-EP and the Standard Gyrex Privilege are the size of the magnet, the size of the gradient coils, and the size of the Body Coil. All performance specifications are identical in the two systems.

4. Safety Analysis

The Bo is the same as in the predicate device, and the SAR, dB/dt, and acoustic noise have changed, but remain below the levels of concern defined by the IEC 601-2-33 final draft. The gradient coils and Body Coil comply with appropriate safety standards.

All patient contacting materials in the Gyrex V-EP are identical to those in the predicate device, and no new safety hazards related to Site Planning, Installation, and Service, or requirements for safety related labeling were introduced.

5. Effectiveness Comparison

The performance specifications of the Gyrex V-EP are identical to those of the predicate device.

6. Substantial Equivalency Statement

It is Elscint's opinion that the Gyrex V-EP is substantially equivalent in safety and effectiveness to its predicate device.