SUMMARY OF SAFETY AND EFFECTIVENESS

K970005

1. Device Name: Gyrex 2T Prestige ^{1}H Spectroscopy Option.

1.2 Classification Name: Magnetic Resonance Diagnostic Device

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

MAR 28 1997

1.4 510(k) Number:_____.

2. Identification of Predicate Devices: The predicate devices are the Gyrex 2T Prestige System (k945791) and the GE Hydrogen Spectroscopy Option - PROBE (k930265).

3. Modifications to Predicate Device

The current modification to the Gyrex 2T-Prestige consists of the addition of software to enable the production of ^{1}H spectra. The spectra are produced using the existing MRI hardware.

The spectroscopy software includes automated shimming, water suppression, transmitter calibration, central frequency calibration, phase correction and display, and higher level spectral processing functions.

4. Safety Comparison

The B_0, dB/dt, and accoustic noise are unaffected by the current modification , and the maximum SAR is the same as for the predicate device.

All potential software safety hazards were minimized by controlled design, and testing.

No electrical, mechanical, biocompatibility, site planning, installation, or service hazards, or requirements for safety related labeling were introduced by this modification.

5. Effectiveness Comparison

The effectiveness of the system is similar to that of the GE Hydrogen Spectroscopy Option - PROBE (the predicate device).

6. Substantial Equivalency Statement

The FDA recommended MRI safety limits are not exceeded, and the effectiveness of the device is similar to that of the predicate devices. It is Elscint's opinion that the 2T Prestige with the ^{1}H Spectroscopy Option is substantially equivalent in safety and effectiveness to its predicate devices.