

SEP 20 1996

Summary of Safety and Effectiveness

K962677

The following information is made available pursuant to the requirements of the Safe Medical devices Act of 1990.

1. **Submitter:** Elscint MR, Inc.
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2. **Trade/Proprietary Name:** Esteem 1.5T MRI System
Common Name: Magnetic Resonance Imaging System
Classification Name: Magnetic Resonance Diagnostic Device
3. **Predicate device:** Esteem 1.5T MRI System (described in **K942953**)

4. **Device Description:**

The Elscint Esteem 1.5T MRI system is designed as a general purpose whole-body MRI system for producing cross-sectional images of the internal structures of the head, body or extremities in transverse, sagittal, coronal or oblique planes. The images produced by the MR system reflect the spatial distribution of protons (hydrogen nuclei) and image appearance is determined by proton density, NMR relaxation time (T1 and T2) and flow. When interpreted by a trained physician, these images yield information that can be useful in determination of a diagnosis, surgery planning or therapy planning.

The major components changed or updated over that described in the predicate device submission are:

- A semi-flexible 4-element receive-only phased array pelvic coil for improved pelvic imaging.
- A semi-flexible 4-element receive-only phased array body coil for improved imaging of the liver, kidneys and hips.
- Additional receive-only surface coils for imaging the spine, shoulder, pelvis, and temporomandibular joint:

