Summary of Safety and Effectiveness

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

1. Submitter: Elscint MR, Inc.
   2555 Midpoint Drive
   Fort Collins, CO 80521
   Tel: (970) 498-8088
   Fax: (970) 498-8098

   Contact: Elizabeth F. Lowder, Director of Quality and Programs

   Date: July 3, 1996

2. Product Indentification: Elscint Gyrex Eteem 1.5T MRI System, Software Version 5.0 Upgrade
3. Predicate Device: Esteem 1.5T MRI System

4. Device Description and Indications for Use:

   The Elscint MR, Inc. Esteem Whole Body MR Imaging System is a 1.5 Tesla Magnetic Resonance Imaging System 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 times (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.

5. Comparison to Predicate Device

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

   - A higher performance gradient amplifier and a water-cooled gradient that when utilized together provide a peak strength of 29mT/M and a slew rate of 60mT/M/msec,
   - An ECG monitoring unit to allow pulse sequences gated to the cardiac cycle to provide cardiac and pulmonary images with reduced artifact from heart motion,
   - The addition of a phased array spine RF coil for increased FOV coverage in the z-direction,
   - Additional flexibility added to existing user interface software

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 15 1997

Elizabeth F. Lowder
Director of Quality Programs
Elscint MR, Inc.
2555 Midpoint Drive
Fort Collins, CO 80525

Re: K972826
Software Version 5.0 Upgrade for Elscint
Gyrex Esteem 1.5T MRI System
Dated: Undated
Received: July 29, 1997
Regulatory class: II
21 CFR 892.1000/Procode: 90 LNH

Dear Ms. Lowder:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirement, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4613. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsmamain.html".

Sincerely yours,

Lillian Yin

Lillian Yin, Ph.D.
Director, Division of Reproductive,
Abdominal, Ear, Nose and Throat,
and Radiological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Elscint MR, Inc.

Elscint

510(k) number K962677

Device Name: Gyrex Esteem 1.5T MRI System

Indications for Use:

The Gyrex Esteem 1.5T MRI System is a general purpose whole-body MRI system that produces images of the internal structures of the head, body, or extremities. The indications for use are not dissimilar to established indications for use for other general purpose whole-body MRI systems. The established indications for use are that when interpreted by a trained physician, MRI can be useful in determination of a diagnosis, surgery planning, or therapy planning and is used in a clinic or hospital setting.

The SW Version 5.0 upgrade does not change or contain any additional indications for use.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over the Counter Use _____
(Per CRF 801.109)

(Optional Format 1-2-96)

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT,
and Radiological Devices
510(k) Number K972826