510(k) Summary

K980306

1. **Submitter's Name and Address:** Elscint, Inc., 505 Main Street, Hackensack, NJ 07601

   Contact Person and Telephone No.: Steven M. Kay, (201) 342-2020

   Date of Summary: 11 January, 1998

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2. **Device Name:** Elscint MRI Software Version 3.0
   Trade/Proprietary Name: Elscint MRI Software Version 3.0
   Common Name: MRI System
   Classification Name: Magnetic Resonance Diagnostic Device

3. **Predicate Device(s):** Gyrex 2T Prestige (k945791),
   Gyrex Privilege (k954039),
   Gyrex V-EP (k962618),
   Gyrex Prima 1TG (k970990)

4. **Device Description:**

The modifications include: new imaging sequences: FSAGE, Multishot EPI, Long ETL FSE, SSE, SSV, and diffusion weighted imaging, automated image filtering, MPR, PCA color coded velocity maps, Time Lapse post processing, Real-Time Localizer, double oblique localization, and multiple presaturation.

5. **Intended Use:**
   Anatomical Region: Whole Body and Organ Specific imaging
   Nuclei Excited: Hydrogen
   Diagnostic Use: The production of Magnetic Resonance Images

6. **Safety:**

The SAR, dB/dt, acoustic noise, and Bo are the same as the predicate devices.

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

7. Effectiveness:

Acquisition Parameter Comparison

	Version 3.0	Predicate Devices
Minimum TE	2ms	4.3ms
Minimum TR	7ms	11ms
Minimum FOV	4cm	6.4cm
Maximum 2D Acquisition Matrix	1024^2	512^2
Maximum 3D Acquisition Matrix	256^3 or 128x512x512	256^3 or 128x512x512
Maximum Number of Echoes	8	8
Maximum Number of Slices	80	80
Minimum Slice Width	0.5mm	0.7mm

The system performance parameters are not protocol dependent, and no acquisition software or hardware modifications which affect the system performance parameters are included in Version 3.0. The system performance parameters are therefore not affected by the current modification.

8. Equivalency Information Summary:

The FDA recommended MRI safety limits are not exceeded, and the effectiveness of the devices is improved in non-substantial ways from that of the predicate devices. It is Elscint's opinion that the Elscint MRI Systems with Software Version 3.0 are substantially equivalent in safety and effectiveness to their predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

APR - 2 1998

Steven M. Kay
Director, Regulatory Affairs and
Quality Assurance
Elscint, Inc.
505 Main Street
Hackensack, NJ 07601

Re: K980306
Software Version 3.0 for the Gyrex
Magnetic Resonance Imaging Systems
Dated: January 23, 1998
Received: January 27, 1998
Regulatory class: II
21 CFR 892.1000/Procode: 90 LNH

Dear Mr. Kay:

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 requirements, 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/dsma/dsmamain.html".

Sincerely yours,

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

510(k) Number (if known): K980306

Device Name: VERSION 3.0

Indications For Use:

WHOLE BODY MAGNETIC RESONANCE IMAGING

(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 21 CFR 801.109)

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT,
and Radiological Devices
510(k) Number K980306