510(k) Summary

K974614

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 MAR - 4 1998

   Date of Summary: 10 December 1997

2. **Device Name:** Retrospective Gating for Elscint MRI Systems
   Trade/Proprietary Name: Retrospective Gating for Elscint MRI System
   Common Name: MRI System Modification
   Classification Name: Magnetic Resonance Diagnostic Device

3. **Predicate Device(s):** Gyrex 2T Prestige system (K945791), Gyrex Privilege System (K954039), Gyrex Prima 1 TG System (K970990)

4. **Device Description:**
   The modification is a cardiac gating technique referred to as Retrospective Gating. In standard cardiac gating, the acquisition is triggered by the QRS pulse of the ECG. In Retrospective Gating, the scan runs continuously, and the correlation with the QRS cycle is done after the fact. This modification does not involve any changes to the existing hardware of the predicate devices.

5. **Intended Use:**
   Anatomical Region: Heart
   Nuclei Excited: Hydrogen
   Diagnostic Use: Production of a series of images of the heart at different phases of the cardiac cycle.

6. **Safety:**
   - The MRI safety parameters, SAR, dB/dt, B_0, and acoustic noise, are unchanged by the current modification.
   - Electrical, mechanical, and biocompatibility safety issues are unchanged by the current modification.
   - No new software hazards have been introduced, so the software level of concern remains minor.
   - The current modification does not affect the site planning, installation, or service manuals, and do not require any new safety labeling.

7. **Effectiveness:**

   The MRI performance parameters remain unchanged. The Retrospective Gating option produces images that are comparable with those produced using the standard cardiac gating technique.

8. **Equivalency Information Summary:**

   The FDA recommended MRI safety limits are not exceeded, and the effectiveness of the modified devices is similar to that of the predicate devices. It is Elscint's opinion that the Prestige, Privilege and Prima systems with the new Retrospective Gating option are substantially equivalent to their predicate devices in terms of safety and effectiveness.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR - 4 1998

Beny Sherer
Safety Officer
Elscint, Inc.
86 Orchard Street
Hackensack, NJ 07601

Re: K974614
Gyrex 2T Prestige, Privilege and Prima
ITG with Retrospective Gating
Dated: December 10, 1997
Received: December 11, 1997
Regulatory class: II
21 CFR 892.1000/Procode: 90 LNH

Dear Mr. Sherer:

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

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): K974614

Device Name: Retrospective Gating for Elscint MRI Systems

Indications For Use:

The production of a series of images of the heart at different phases of the cardiac cycle.

(Please do not write below this line - continue on another page if needed)

(Concurrence of CDRH, Office of Device Evaluation (ODE))

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT,
and Radiological Devices
510(k) Number K974614

Prescription Use ✓ OR Over-The-Counter Use_____
(Per 21 CFR 801.109)