

**K965044 GYREX 2T PRESTIGE MODEL NO. 100-6321-0107 AND  
GYREX PRIVILEGE MODEL NO. 100-6326-0102**

Jun 16, 1997  
185 days to decision

K965044 · Product code: LNH · Radiology  
Source: <https://www.510kdatabase.net/k965044/>

**SUBMISSION DETAILS**

---

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Nuclear Magnetic Resonance Imaging (LNH)
Date received	Dec 13, 1996
Decision date	Jun 16, 1997
Days to decision	185 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

---

Company	<b>Elscint, Inc.</b>
Location	Mchenry, IL, US
Contact	THOMAS J SPACKMAN
510(k) history	94 submissions · 94 cleared · 1981-1998

---

510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)

Device record: <https://www.510kdatabase.net/k965044/>; Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://accessdata.fda.gov)).

510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at [accessdata.fda.gov](http://accessdata.fda.gov). - Generated May 19, 2026