

**K942953 ORACLE MRI WHOLE BODY MR IMAGING SYSTEM**Sep 30, 1994  
100 days to decisionK942953 · Product code: **LNH** · Radiology  
Source: <https://www.510kdatabase.net/k942953/>**SUBMISSION DETAILS**

---

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Nuclear Magnetic Resonance Imaging (LNH)
Date received	Jun 22, 1994
Decision date	Sep 30, 1994
Days to decision	100 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

---

Company	<b>Otsuka Electronics USA, Inc.</b>
Location	Fort Collins, CO, US
Contact	G. NEIL HOLLAND
510(k) history	2 submissions · 2 cleared · 1994-1994

---

510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k942953/> 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 20, 2026