

**K151015 ECHELON Oval V 5.0 MRI System**Jul 29, 2015  
104 days to decisionK151015 · Product code: **LNH** · Radiology  
Source: <https://www.510kdatabase.net/k151015/>**SUBMISSION DETAILS**

---

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Nuclear Magnetic Resonance Imaging (LNH)
Date received	Apr 16, 2015
Decision date	Jul 29, 2015
Days to decision	104 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

---

Company	<b>Hitachi Medical Systems America, Inc.</b>
Location	Twinsburg, OH, US
Contact	DOUG THISTLETHWAITE
510(k) history	100 submissions · 100 cleared · 1991-2017

---

510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k151015/> 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 16, 2026