

K083137 NEURO III-SVDec 16, 2008
54 days to decisionK083137 · Product code: **LNH** · Radiology
Source: <https://www.510kdatabase.net/k083137/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Nuclear Magnetic Resonance Imaging (LNH)
Date received	Oct 23, 2008
Decision date	Dec 16, 2008
Days to decision	54 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Imris, Inc.
Location	Rockville, MD, US
Contact	THOMAS M TSAKERIS
510(k) history	14 submissions · 14 cleared · 2006-2015

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k083137/> Data sourced from FDA 510(k) public records (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. - Generated May 17, 2026