

K083533 ECHELON C MRI SYSTEM

Feb 17, 2009
81 days to decision

K083533 · Product code: **LNH** · Radiology
Source: <https://www.510kdatabase.net/k083533/>

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Nuclear Magnetic Resonance Imaging (LNH)
Date received	Nov 28, 2008
Decision date	Feb 17, 2009
Days to decision	81 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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

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Device record: <https://www.510kdatabase.net/k083533/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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