

K133986 1.5T ORBIT AND MANDIBLE ARRAY, 3.0T ORBIT AND MANDIBLE ARRAYJan 27, 2014
32 days to decisionK133986 · Product code: **MOS** · Radiology
Source: <https://www.510kdatabase.net/k133986/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Coil, Magnetic Resonance, Specialty (MOS)
Date received	Dec 26, 2013
Decision date	Jan 27, 2014
Days to decision	32 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Resonance Innovations, LLC
Location	Omaha, NE, US
Contact	RANDALL JONES
510(k) history	8 submissions · 8 cleared · 2006-2014

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k133986/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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