

K994378 AIRIS IIMar 7, 2000
71 days to decisionK994378 · Product code: **MOS** · Radiology
Source: <https://www.510kdatabase.net/k994378/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Coil, Magnetic Resonance, Specialty (MOS)
Date received	Dec 27, 1999
Decision date	Mar 7, 2000
Days to decision	71 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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

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