

K984280 AIRIS II MAGNETIC RESONANCE DIAGNOSTIC DEVICE,INTERVENTIONAL MR PACKAGE

Feb 8, 1999
70 days to decision

K984280 · Product code: LNH · Radiology
Source: <https://www.510kdatabase.net/k984280/>

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Nuclear Magnetic Resonance Imaging (LNH)
Date received	Nov 30, 1998
Decision date	Feb 8, 1999
Days to decision	70 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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

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Device record: <https://www.510kdatabase.net/k984280/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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