FDA 510(k) Premarket Notification

K032232 AIRIS ELITE MAGNETIC RESONANCE IMAGING DEVICE

CLEARED

Sep 29, 2003
70 days to decision

K032232 · Product code: **LNH** · Radiology
Source: https://www.510kdatabase.net/k032232/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Abbreviated
Device classification	System, Nuclear Magnetic Resonance Imaging (LNH)
Date received	Jul 21, 2003
Decision date	Sep 29, 2003
Days to decision	70 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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