FDA 510(k) Premarket Notification

K012154 AURORA MAGNETIC RESONANCE DIAGNOSTIC DEVICE

CLEARED

Sep 19, 2001
70 days to decision

K012154 · Product code: **LNH** · Radiology
Source: https://www.510kdatabase.net/k012154/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Nuclear Magnetic Resonance Imaging (LNH)
Date received	Jul 11, 2001
Decision date	Sep 19, 2001
Days to decision	70 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Aurora Imaging Technology, Inc.**
Location	Wilmington, MA, US
Contact	JAMES J ROGERS
510(k) history	7 submissions · 7 cleared · 2001-2008