FDA 510(k) Premarket Notification

K003575 MODIFICATION TO 3.0T SIGNA VH/I MAGNETIC RESONANCE SYSTEM

CLEARED

Jan 17, 2001
58 days to decision

K003575 · Product code: **LNI** · Radiology
Source: https://www.510kdatabase.net/k003575/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Nuclear Magnetic Resonance Spectroscopic (LNI)
Date received	Nov 20, 2000
Decision date	Jan 17, 2001
Days to decision	58 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**GE Medical Systems**
Location	Milwaukee, WI, US
Contact	LARRY A KROGER
510(k) history	169 submissions · 166 cleared · 1989-2022