

K002997 FIESTA IMAGING OPTIONApr 11, 2001
197 days to decisionK002997 · Product code: **LNH** · Radiology
Source: <https://www.510kdatabase.net/k002997/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Nuclear Magnetic Resonance Imaging (LNH)
Date received	Sep 26, 2000
Decision date	Apr 11, 2001
Days to decision	197 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

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