FDA 510(k) Premarket Notification

CLEARED

K132376 DISCOVERY MR750 3.0T, DISCOVERY MR450 1.5T, DISCOVERY MR750W 3.0T, OPTIMA MR450W 1.5T

Nov 15, 2013
108 days to decision

K132376 · Product code: **LNH** · Radiology
Source: https://www.510kdatabase.net/k132376/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Nuclear Magnetic Resonance Imaging (LNH)
Date received	Jul 30, 2013
Decision date	Nov 15, 2013
Days to decision	108 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Ge Healthcare (Ge Medical Systems, LLC)**
Location	Waukesha, WI, US
Contact	MICHELLE HUETTNER
510(k) history	6 submissions · 6 cleared · 2013-2022