FDA 510(k) Premarket Notification

K180100 MRIaudio PREM System

CLEARED

Jun 14, 2018
149 days to decision

K180100 · Product code: **LNH** · Radiology
Source: https://www.510kdatabase.net/k180100/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Nuclear Magnetic Resonance Imaging (LNH)
Date received	Jan 16, 2018
Decision date	Jun 14, 2018
Days to decision	149 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Mriaudio**
Location	Carlsbad, CA, US
Contact	Joe Caruso
510(k) history	1 submissions · 1 cleared · 2018-2018

510k Database - www.510kdatabase.net
Device record: https://www.510kdatabase.net/k180100/ Data sourced from FDA 510(k) public records (accessdata.fda.gov).
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