FDA 510(k) Premarket Notification

K210843 STAGE

CLEARED

Jun 29, 2021
99 days to decision

K210843 · Product code: **LNH** · Radiology
Source: https://www.510kdatabase.net/k210843/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Nuclear Magnetic Resonance Imaging (LNH)
Date received	Mar 22, 2021
Decision date	Jun 29, 2021
Days to decision	99 days
Third-party review	Yes
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Spintech, Inc.**
Location	Minneapolis, MN, US
Contact	Kay Fuller
510(k) history	10 submissions · 10 cleared · 1992-2022

REGULATORY CONSULTANT

Consulting firm	**Regulatory Technology Services, LLC**
Contact	Prithul Bom

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: FDA accessdata.fda.gov