

K192650 i_Space 1.5T Superconducting Magnetic Resonance Imaging SystemJan 29, 2021
493 days to decisionK192650 · Product code: LNH · Radiology
Source: <https://www.510kdatabase.net/k192650/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Nuclear Magnetic Resonance Imaging (LNH)
Date received	Sep 24, 2019
Decision date	Jan 29, 2021
Days to decision	493 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Mri Division,Beijing Wandong Medical Technology Co., Ltd.
Location	Beijing, CN
Contact	Zhou Lu
510(k) history	2 submissions · 2 cleared · 2021-2022

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