

K211980 SIGNA PrimeJan 16, 2022
205 days to decisionK211980 · Product code: **LNH** · Radiology
Source: <https://www.510kdatabase.net/k211980/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Nuclear Magnetic Resonance Imaging (LNH)
Date received	Jun 25, 2021
Decision date	Jan 16, 2022
Days to decision	205 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Ge Healthcare (Tianjin) Company Limited
Location	Tianjin, CN
Contact	Huande Li
510(k) history	6 submissions · 6 cleared · 2019-2024

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