

K223439 SIGNA VictorFeb 13, 2023
91 days to decisionK223439 · Product code: **LNH** · Radiology
Source: <https://www.510kdatabase.net/k223439/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Nuclear Magnetic Resonance Imaging (LNH)
Date received	Nov 14, 2022
Decision date	Feb 13, 2023
Days to decision	91 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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k223439/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at accessdata.fda.gov. - Generated May 14, 2026