

**K233728 SIGNA Champion**Jan 19, 2024  
59 days to decisionK233728 · Product code: **LNH** · Radiology  
Source: <https://www.510kdatabase.net/k233728/>**SUBMISSION DETAILS**

---

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Nuclear Magnetic Resonance Imaging (LNH)
Date received	Nov 21, 2023
Decision date	Jan 19, 2024
Days to decision	59 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

---

Company	<b>Ge Healthcare (Tianjin) Company Limited</b>
Location	Tianjin, CN
Contact	Xinyu Song
510(k) history	6 submissions · 6 cleared · 2019-2024

**REGULATORY CONSULTANT**

---

Consulting firm	<b>Ge Medical Systems, LLC</b>
Contact	Glen Sabin

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

---

510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k233728/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](https://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](https://accessdata.fda.gov). - Generated May 13, 2026