

**K143345 SIGNA Pioneer**Jul 10, 2015  
231 days to decisionK143345 · Product code: **LNH** · Radiology  
Source: <https://www.510kdatabase.net/k143345/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Nuclear Magnetic Resonance Imaging (LNH)
Date received	Nov 21, 2014
Decision date	Jul 10, 2015
Days to decision	231 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Ge Healthcare Japan Corporation</b>
Location	Hino-Shi, Tokyo, JP
Contact	Toru Shimizu
510(k) history	10 submissions · 10 cleared · 2011-2026

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k143345/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://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](http://accessdata.fda.gov). - Generated May 14, 2026