

**K232032 PROBEAT-FR**Jan 12, 2024  
189 days to decisionK232032 · Product code: **LHN** · Radiology  
Source: <https://www.510kdatabase.net/k232032/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Radiation Therapy, Charged-particle, Medical (LHN)
Date received	Jul 7, 2023
Decision date	Jan 12, 2024
Days to decision	189 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Hitachi, Ltd. Radiation Oncology Systems, Kashiwanoha</b>
Location	Kashiwa-Shi, JP
Contact	Tomoko Irisa
510(k) history	2 submissions · 2 cleared · 2022-2024

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k232032/> 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 13, 2026