

**K152592 PROBEAT-V**Nov 2, 2015  
53 days to decisionK152592 · Product code: **LHN** · Radiology  
Source: <https://www.510kdatabase.net/k152592/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Radiation Therapy, Charged-particle, Medical (LHN)
Date received	Sep 10, 2015
Decision date	Nov 2, 2015
Days to decision	53 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Hitachi, Ltd., Health Care Company</b>
Location	Tokyo, JP
Contact	NAOYA NISHIMURA
510(k) history	4 submissions · 4 cleared · 2015-2016

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k152592/> 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 16, 2026