

K153614 PROBEAT-V and accessoriesApr 21, 2016
126 days to decisionK153614 · Product code: **LHN** · Radiology
Source: <https://www.510kdatabase.net/k153614/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Radiation Therapy, Charged-particle, Medical (LHN)
Date received	Dec 17, 2015
Decision date	Apr 21, 2016
Days to decision	126 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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

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