

K152207 Extended Range Shifter for PROBEAT-VOct 2, 2015
57 days to decisionK152207 · Product code: **LHN** · Radiology
Source: <https://www.510kdatabase.net/k152207/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Radiation Therapy, Charged-particle, Medical (LHN)
Date received	Aug 6, 2015
Decision date	Oct 2, 2015
Days to decision	57 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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