

**K161163 PROBEAT-V Proton Beam Therapy System with X-ray
Limiting Accessory**Jul 13, 2016
79 days to decisionK161163 · Product code: LHN · Radiology
Source: <https://www.510kdatabase.net/k161163/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Radiation Therapy, Charged-particle, Medical (LHN)
Date received	Apr 25, 2016
Decision date	Jul 13, 2016
Days to decision	79 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Hitachi , Ltd.
Location	Washington, Dc, DC, US
Contact	Naoya Nishimura
510(k) history	8 submissions · 8 cleared · 2006-2020

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k161163/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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