

K171049 Real Time Image Gating System for Proton Beam Therapy SystemsDec 26, 2017
263 days to decisionK171049 · Product code: **LHN** · Radiology
Source: <https://www.510kdatabase.net/k171049/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Radiation Therapy, Charged-particle, Medical (LHN)
Date received	Apr 7, 2017
Decision date	Dec 26, 2017
Days to decision	263 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Hitachi, Ltd. Healthcare
Location	Tokyo, JP
Contact	Tomoyuki Seino
510(k) history	1 submissions · 1 cleared · 2017-2017

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k171049/>; Data sourced from FDA 510(k) public records (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. - Generated May 16, 2026