

K160612 Sumitomo Proton Therapy SystemAug 17, 2016
167 days to decisionK160612 · Product code: **LHN** · Radiology
Source: <https://www.510kdatabase.net/k160612/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Radiation Therapy, Charged-particle, Medical (LHN)
Date received	Mar 3, 2016
Decision date	Aug 17, 2016
Days to decision	167 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Sumitomo Heavy Industries, Ltd.
Location	San Diego, CA, US
Contact	KATSUHIRO NARASAKI
510(k) history	2 submissions · 2 cleared · 2013-2016

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