

K191521 Radiance 330 Proton Beam Therapy SystemSep 27, 2019
112 days to decisionK191521 · Product code: **LHN** · Radiology
Source: <https://www.510kdatabase.net/k191521/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Radiation Therapy, Charged-particle, Medical (LHN)
Date received	Jun 7, 2019
Decision date	Sep 27, 2019
Days to decision	112 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Protom International Holding Corporation
Location	Wakefield, MA, US
Contact	Stephen L. Spotts
510(k) history	1 submissions · 1 cleared · 2019-2019

REGULATORY CONSULTANT

Consulting firm	Hogan Lovells US LLP
Contact	Jonathan Kahan

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: [FDA accessdata.fda.gov](https://accessdata.fda.gov)

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