

K220883 Small Field ApplicatorDec 15, 2022
265 days to decisionK220883 · Product code: **LHN** · Radiology
Source: <https://www.510kdatabase.net/k220883/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Radiation Therapy, Charged-particle, Medical (LHN)
Date received	Mar 25, 2022
Decision date	Dec 15, 2022
Days to decision	265 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Hitachi, Ltd. Radiation Oncology Systems, Kashiwanoha
Location	Kashiwa-Shi, JP
Contact	Tomoyuki Seino
510(k) history	2 submissions · 2 cleared · 2022-2024

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

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