

K242418 P-Cure Proton Therapy System (PPTS)May 12, 2025
270 days to decisionK242418 · Product code: **LHN** · Radiology
Source: <https://www.510kdatabase.net/k242418/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Radiation Therapy, Charged-particle, Medical (LHN)
Date received	Aug 15, 2024
Decision date	May 12, 2025
Days to decision	270 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	P-Cure, Ltd.
Location	Netanya, Hasharon, IL
Contact	Ori Lubin
510(k) history	4 submissions · 4 cleared · 2010-2025

REGULATORY CONSULTANT

Consulting firm	Hogan Lovells US LLP
Contact	Lina Kontos

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

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