

K221996 P-Cure Proton Beam Therapy SystemMar 20, 2023
257 days to decisionK221996 · Product code: **LHN** · Radiology
Source: <https://www.510kdatabase.net/k221996/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Radiation Therapy, Charged-particle, Medical (LHN)
Date received	Jul 6, 2022
Decision date	Mar 20, 2023
Days to decision	257 days
Third-party review	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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k221996/> 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 27, 2026