

**K250986 S250-FIT Proton Beam Radiation Therapy Device
(S250-FIT)**Sep 12, 2025
165 days to decisionK250986 · Product code: **LHN** · Radiology
Source: <https://www.510kdatabase.net/k250986/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Radiation Therapy, Charged-particle, Medical (LHN)
Date received	Mar 31, 2025
Decision date	Sep 12, 2025
Days to decision	165 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Mevion Medical Systems, Inc.
Location	Littleton, MA, US
Contact	Jason Brown
510(k) history	2 submissions · 2 cleared · 2025-2026

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k250986/> 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 14, 2026