

**K253406 S250-FIT Proton Beam Radiation Therapy Device
(S250-FIT)**Mar 25, 2026
176 days to decisionK253406 · Product code: **LHN** · Radiology
Source: <https://www.510kdatabase.net/k253406/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Radiation Therapy, Charged-particle, Medical (LHN)
Date received	Sep 30, 2025
Decision date	Mar 25, 2026
Days to decision	176 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

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