

K250064 Dose+ (1.0)Sep 4, 2025
237 days to decisionK250064 · Product code: **MUJ** · Radiology
Source: <https://www.510kdatabase.net/k250064/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Planning, Radiation Therapy Treatment (MUJ)
Date received	Jan 10, 2025
Decision date	Sep 4, 2025
Days to decision	237 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Mvision AI OY
Location	Helsinki, FI
Contact	Kalpana Jha
510(k) history	2 submissions · 2 cleared · 2024-2025

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k250064/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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