

K253050 RadOncAIJun 18, 2026
269 days to decisionK253050 · Product code: **MUJ** · Radiology
Source: <https://www.510kdatabase.net/k253050/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Planning, Radiation Therapy Treatment (MUJ)
Date received	Sep 22, 2025
Decision date	Jun 18, 2026
Days to decision	269 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Informai
Location	Houston, TX, US
Contact	Jim Havelka
510(k) history	1 submissions · 1 cleared · 2026-2026

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