

K253091 ART-Plan+ (v3.1.0)Dec 23, 2025
91 days to decisionK253091 · Product code: **MUJ** · Radiology
Source: <https://www.510kdatabase.net/k253091/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Planning, Radiation Therapy Treatment (MUJ)
Date received	Sep 23, 2025
Decision date	Dec 23, 2025
Days to decision	91 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Therapanacea Sas
Location	Paris, FR
Contact	Ajachandra Bhairavi
510(k) history	4 submissions · 4 cleared · 2023-2025

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k253091/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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