FDA 510(k) Premarket Notification

K250318 Planmed XFI

CLEARED

Sep 26, 2025
234 days to decision

K250318 · Product code: **SFV** · Radiology
Source: https://www.510kdatabase.net/k250318/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	X-ray, Computed Tomography, Cone-beam (SFV)
Date received	Feb 4, 2025
Decision date	Sep 26, 2025
Days to decision	234 days
Third-party review	Yes
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Planmed OY**
Location	Helsinki, FI
Contact	Niina Vuorikallas
510(k) history	20 submissions · 20 cleared · 1992-2025

REGULATORY CONSULTANT

Consulting firm	**Regulatory Technology Services, LLC**
Contact	Prithul Bom

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: FDA accessdata.fda.gov

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Device record: https://www.510kdatabase.net/k250318/ Data sourced from FDA 510(k) public records (accessdata.fda.gov).
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