

K213278 Planmed VerityApr 28, 2022
209 days to decisionK213278 · Product code: **OAS** · Radiology
Source: <https://www.510kdatabase.net/k213278/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	X-ray, Tomography, Computed, Dental (OAS)
Date received	Oct 1, 2021
Decision date	Apr 28, 2022
Days to decision	209 days
Third-party review	No
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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k213278/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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