

K230985 Planmeca VisoDec 28, 2023
266 days to decisionK230985 · Product code: **OAS** · Radiology
Source: <https://www.510kdatabase.net/k230985/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	X-ray, Tomography, Computed, Dental (OAS)
Date received	Apr 6, 2023
Decision date	Dec 28, 2023
Days to decision	266 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Planmeca Oy
Location	Helsinki, FI
Contact	Niina Vuorikallas
510(k) history	28 submissions · 28 cleared · 1993-2023

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k230985/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at accessdata.fda.gov. - Generated May 14, 2026