FDA 510(k) Premarket Notification

K230985 Planmeca Viso

CLEARED

Dec 28, 2023
266 days to decision

K230985 · 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