FDA 510(k) Premarket Notification

CLEARED

K160506 Planmeca ProMax 3D Max, Planmeca Maximity

May 20, 2016
86 days to decision

K160506 · Product code: **OAS** · Radiology
Source: https://www.510kdatabase.net/k160506/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	X-ray, Tomography, Computed, Dental (OAS)
Date received	Feb 24, 2016
Decision date	May 20, 2016
Days to decision	86 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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

510k Database - www.510kdatabase.net
Device record: https://www.510kdatabase.net/k160506/ Data sourced from FDA 510(k) public records (accessdata.fda.gov).
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