

K103689 PLANMECA PROMAX 3D MIDMar 17, 2011
90 days to decisionK103689 · Product code: **MUH** · Radiology
Source: <https://www.510kdatabase.net/k103689/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, X-ray, Extraoral Source, Digital (MUH)
Date received	Dec 17, 2010
Decision date	Mar 17, 2011
Days to decision	90 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.netDevice record: <https://www.510kdatabase.net/k103689/> 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