

K171385 Planmeca RomexisNov 14, 2017
187 days to decisionK171385 · Product code: **LLZ** · Radiology
Source: <https://www.510kdatabase.net/k171385/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Image Processing, Radiological (LLZ)
Date received	May 11, 2017
Decision date	Nov 14, 2017
Days to decision	187 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

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