

**K970975 PROSTYLE INTRA**Apr 1, 1997  
15 days to decisionK970975 · Product code: **EHD** · Radiology  
Source: <https://www.510kdatabase.net/k970975/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Unit, X-ray, Extraoral With Timer (EHD)
Date received	Mar 17, 1997
Decision date	Apr 1, 1997
Days to decision	15 days
Third-party review	No
Summary / Statement	Statement

**APPLICANT**

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

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k970975/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://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](http://accessdata.fda.gov). - Generated May 20, 2026