

**K011619 PROMAX, PANORAMIC X-RAY UNIT WITH  
CEPHALOSTAT**Jun 29, 2001  
35 days to decisionK011619 · Product code: **EHD** · Radiology  
Source: <https://www.510kdatabase.net/k011619/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Unit, X-ray, Extraoral With Timer (EHD)
Date received	May 25, 2001
Decision date	Jun 29, 2001
Days to decision	35 days
Third-party review	No
Summary / Statement	Statement

**APPLICANT**

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Company	<b>Planmeca Oy</b>
Location	Helsinki, FI
Contact	BOB PIENKOWSKI
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/k011619/>; Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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