

K000428 DIXI 2Apr 28, 2000
79 days to decisionK000428 · Product code: **EHD** · Radiology
Source: <https://www.510kdatabase.net/k000428/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Unit, X-ray, Extraoral With Timer (EHD)
Date received	Feb 9, 2000
Decision date	Apr 28, 2000
Days to decision	79 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

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

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