

K980581 PLANMECA DIXI, DIGITAL INTRAORAL X-RAY IMAGING SYSTEM

Apr 17, 1998
59 days to decision

K980581 · Product code: **EHD** · Radiology
Source: <https://www.510kdatabase.net/k980581/>

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Unit, X-ray, Extraoral With Timer (EHD)
Date received	Feb 17, 1998
Decision date	Apr 17, 1998
Days to decision	59 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

510k Database - www.510kdatabase.net

Device record: <https://www.510kdatabase.net/k980581/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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