FDA 510(k) Premarket Notification

K000771 DIMAX 2

CLEARED

May 3, 2000
55 days to decision

K000771 · Product code: **EHD** · Radiology
Source: https://www.510kdatabase.net/k000771/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Unit, X-ray, Extraoral With Timer (EHD)
Date received	Mar 9, 2000
Decision date	May 3, 2000
Days to decision	55 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

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