FDA 510(k) Premarket Notification

K033755 MINRAY

CLEARED

Apr 29, 2004
150 days to decision

K033755 · Product code: **EHD** · Radiology
Source: https://www.510kdatabase.net/k033755/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Unit, X-ray, Extraoral With Timer (EHD)
Date received	Dec 1, 2003
Decision date	Apr 29, 2004
Days to decision	150 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Soredex Palodex Group OY**
Location	Helsinki, FI
Contact	KAI LANER
510(k) history	9 submissions · 9 cleared · 2001-2011