FDA 510(k) Premarket Notification

K012170 DIGORA PCT

CLEARED

Aug 10, 2001
29 days to decision

K012170 · Product code: **MUH** · Radiology
Source: https://www.510kdatabase.net/k012170/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, X-ray, Extraoral Source, Digital (MUH)
Date received	Jul 12, 2001
Decision date	Aug 10, 2001
Days to decision	29 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