FDA 510(k) Premarket Notification

K073350 SCANORA 3D

CLEARED

Dec 19, 2007
20 days to decision

K073350 · Product code: **MUH** · Radiology
Source: https://www.510kdatabase.net/k073350/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, X-ray, Extraoral Source, Digital (MUH)
Date received	Nov 29, 2007
Decision date	Dec 19, 2007
Days to decision	20 days
Third-party review	Yes
Summary / Statement	Summary

APPLICANT

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