FDA 510(k) Premarket Notification

K180947 Orthopantomograph OP 3D

CLEARED

Jun 7, 2018
57 days to decision

K180947 · Product code: **OAS** · Radiology
Source: https://www.510kdatabase.net/k180947/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	X-ray, Tomography, Computed, Dental (OAS)
Date received	Apr 11, 2018
Decision date	Jun 7, 2018
Days to decision	57 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Palodex Group OY**
Location	Tuusula, FI
Contact	Terho Turkumaki
510(k) history	10 submissions · 10 cleared · 2012-2024