

K163423 Orthopantomograph OP300Aug 31, 2017
268 days to decisionK163423 · Product code: **OAS** · Radiology
Source: <https://www.510kdatabase.net/k163423/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	X-ray, Tomography, Computed, Dental (OAS)
Date received	Dec 6, 2016
Decision date	Aug 31, 2017
Days to decision	268 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k163423/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at accessdata.fda.gov. - Generated May 26, 2026