

**K122018 OP300**Dec 10, 2012  
153 days to decisionK122018 · Product code: **OAS** · Radiology  
Source: <https://www.510kdatabase.net/k122018/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	X-ray, Tomography, Computed, Dental (OAS)
Date received	Jul 10, 2012
Decision date	Dec 10, 2012
Days to decision	153 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Palodex Group OY</b>
Location	Tuusula, FI
Contact	MATTI TULIKOURA
510(k) history	10 submissions · 10 cleared · 2012-2024

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k122018/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://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](http://accessdata.fda.gov). - Generated May 26, 2026