

**K133231 DIGORA OPTIME**Mar 20, 2014  
150 days to decisionK133231 · Product code: **MUH** · Radiology  
Source: <https://www.510kdatabase.net/k133231/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	System, X-ray, Extraoral Source, Digital (MUH)
Date received	Oct 21, 2013
Decision date	Mar 20, 2014
Days to decision	150 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Instrumentarium Dental, Palodex Group OY</b>
Location	Tuusula, FI
Contact	TERHO TURKUMAKI
510(k) history	5 submissions · 5 cleared · 2007-2014

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k133231/> 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 16, 2026