

**K130443 I-MAX TOUCH 3D**Jun 14, 2013  
113 days to decisionK130443 · Product code: **OAS** · Radiology  
Source: <https://www.510kdatabase.net/k130443/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Abbreviated
Device classification	X-ray, Tomography, Computed, Dental (OAS)
Date received	Feb 21, 2013
Decision date	Jun 14, 2013
Days to decision	113 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Owandy</b>
Location	Ormond Beach, FL, US
Contact	Claude Berthoin
510(k) history	6 submissions · 6 cleared · 2006-2014

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k130443/> 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