

**K083917 X-RAY, TOMOGRAPHY, COMPUTED, DENTAL**Jun 2, 2009  
154 days to decisionK083917 · Product code: **OAS** · Radiology  
Source: <https://www.510kdatabase.net/k083917/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	X-ray, Tomography, Computed, Dental (OAS)
Date received	Dec 30, 2008
Decision date	Jun 2, 2009
Days to decision	154 days
Third-party review	No
Summary / Statement	Statement

**APPLICANT**

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Company	<b>Suni Medical Imaging, Inc.</b>
Location	San Jose, CA, US
Contact	AL BETTENCOURT
510(k) history	4 submissions · 4 cleared · 2006-2016

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k083917/> 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