

**K182805 RCT800**Dec 14, 2018  
73 days to decisionK182805 · Product code: **OAS** · Radiology  
Source: <https://www.510kdatabase.net/k182805/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	X-ray, Tomography, Computed, Dental (OAS)
Date received	Oct 2, 2018
Decision date	Dec 14, 2018
Days to decision	73 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Ray Co., Ltd.</b>
Location	Beverly Hills, CA, US
Contact	Changhwan Lee
510(k) history	24 submissions · 24 cleared · 2013-2026

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k182805/> 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 14, 2026