

K181452 RCT800Jul 27, 2018
56 days to decisionK181452 · Product code: **OAS** · Radiology
Source: <https://www.510kdatabase.net/k181452/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	X-ray, Tomography, Computed, Dental (OAS)
Date received	Jun 1, 2018
Decision date	Jul 27, 2018
Days to decision	56 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k181452/> Data sourced from FDA 510(k) public records (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. - Generated May 16, 2026