

K213226 RCT700Nov 29, 2021
61 days to decisionK213226 · Product code: **OAS** · Radiology
Source: <https://www.510kdatabase.net/k213226/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	X-ray, Tomography, Computed, Dental (OAS)
Date received	Sep 29, 2021
Decision date	Nov 29, 2021
Days to decision	61 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k213226/> 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 13, 2026