

K222219 R2 Studio Q/RCT820Dec 6, 2022
134 days to decisionK222219 · Product code: **OAS** · Radiology
Source: <https://www.510kdatabase.net/k222219/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	X-ray, Tomography, Computed, Dental (OAS)
Date received	Jul 25, 2022
Decision date	Dec 6, 2022
Days to decision	134 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Megagen Implant Co., Ltd.
Location	Santa Fe Springs, CA, US
Contact	Yong Jae Kim
510(k) history	31 submissions · 31 cleared · 2008-2025

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