

K200271 rainbow CTApr 16, 2021
437 days to decisionK200271 · Product code: **OAS** · Radiology
Source: <https://www.510kdatabase.net/k200271/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	X-ray, Tomography, Computed, Dental (OAS)
Date received	Feb 4, 2020
Decision date	Apr 16, 2021
Days to decision	437 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Dentium Co., Ltd (Ict Branch)
Location	Suwon-Si, KR
Contact	Sangwoo Lee
510(k) history	4 submissions · 4 cleared · 2020-2023

REGULATORY CONSULTANT

Consulting firm	Mtechgroup
Contact	Dave Kim

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: FDA accessdata.fda.gov510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k200271/> 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 25, 2026