

K251842 Dental Computed Tomography X-ray SystemNov 13, 2025
150 days to decisionK251842 · Product code: **OAS** · Radiology
Source: <https://www.510kdatabase.net/k251842/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	X-ray, Tomography, Computed, Dental (OAS)
Date received	Jun 16, 2025
Decision date	Nov 13, 2025
Days to decision	150 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Fussen Technology Co., Ltd.
Location	Shenzhen, CN
Contact	Guiqin Zheng
510(k) history	1 submissions · 1 cleared · 2025-2025

REGULATORY CONSULTANT

Consulting firm	Landlink Healthcare Technology (Shanghai) Co., Ltd.
Contact	Kyra Kang

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: [FDA accessdata.fda.gov](https://accessdata.fda.gov)

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