

K250839 Dental X-ray SystemJun 11, 2026
448 days to decisionK250839 · Product code: **OAS** · Radiology
Source: <https://www.510kdatabase.net/k250839/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	X-ray, Tomography, Computed, Dental (OAS)
Date received	Mar 20, 2025
Decision date	Jun 11, 2026
Days to decision	448 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Changzhou Boen Zhongding Medical Technology Co., Ltd.
Location	Changzhou, CN
Contact	Shuo Huang
510(k) history	1 submissions · 1 cleared · 2026-2026

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