

K243130 Integral Dental UnitJun 27, 2025
270 days to decisionK243130 · Product code: **EIA** · Dental
Source: <https://www.510kdatabase.net/k243130/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Unit, Operative Dental (EIA)
Date received	Sep 30, 2024
Decision date	Jun 27, 2025
Days to decision	270 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Guangdong Yadeng Medical Apparatus Co., Ltd.,
Location	Foshan, CN
Contact	Chang Ming Weng
510(k) history	1 submissions · 1 cleared · 2025-2025

REGULATORY CONSULTANT

Consulting firm	Guangdong Jianda Medical Technology Co., Ltd.
Contact	Jett Lee

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: [FDA accessdata.fda.gov](https://accessdata.fda.gov)510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k243130/> 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