

K231845 Dental unit Model: MareFeb 28, 2024
251 days to decisionK231845 · Product code: **EIA** · Dental
Source: <https://www.510kdatabase.net/k231845/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Unit, Operative Dental (EIA)
Date received	Jun 22, 2023
Decision date	Feb 28, 2024
Days to decision	251 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Foshan Safety Medical Equipment Co., Ltd.
Location	Foshan, CN
Contact	May Xian
510(k) history	1 submissions · 1 cleared · 2024-2024

REGULATORY CONSULTANT

Consulting firm	Qimmiq Medical Consulting Service Co., Ltd.
Contact	You Yijie

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/k231845/> 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 14, 2026