FDA 510(k) Premarket Notification

K231845 Dental unit Model: Mare

CLEARED

Feb 28, 2024
251 days to decision

K231845 · 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