

K251388 Dental air-motor handpiece (TM-203B2, TM-203M4, TM-205B2, TM-205M4, TM-IS, TM-ES, TM-SG20, TM-X25, TM-BB, TM-IC, TM-RA41)Jan 12, 2026
252 days to decisionK251388 · Product code: **EFB** · Dental
Source: <https://www.510kdatabase.net/k251388/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Handpiece, Air-powered, Dental (EFB)
Date received	May 5, 2025
Decision date	Jan 12, 2026
Days to decision	252 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Foshan Topmed Dental Co., Ltd.
Location	Foshan, CN
Contact	Salon Chen
510(k) history	2 submissions · 2 cleared · 2026-2026

REGULATORY CONSULTANT

Consulting firm	Imd Medical & Drug Technology Service Institutions
Contact	Salon Chen

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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