

K220179 High-Speed Air Turbine Handpieces/Straight Handpieces/Geared Angle Handpieces/Air MotorsSep 22, 2023
609 days to decisionK220179 · Product code: EFB · Dental
Source: <https://www.510kdatabase.net/k220179/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Handpiece, Air-powered, Dental (EFB)
Date received	Jan 21, 2022
Decision date	Sep 22, 2023
Days to decision	609 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Foshan Coxo Medical Instrument Co., Ltd.
Location	Foshan, CN
Contact	Zheng Yongjian
510(k) history	7 submissions · 7 cleared · 2022-2025

REGULATORY CONSULTANT

Consulting firm	Beijing Believe-Med Technology Service Co., Ltd.
Contact	Ray Wang

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: FDA accessdata.fda.gov

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