

K181691 High-speed air turbine handpiece / Low-speed air turbine handpieceMay 26, 2020
699 days to decisionK181691 · Product code: **EFB** · Dental
Source: <https://www.510kdatabase.net/k181691/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Handpiece, Air-powered, Dental (EFB)
Date received	Jun 27, 2018
Decision date	May 26, 2020
Days to decision	699 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Foshan Wenjian Medical Instrument Co., Ltd.
Location	Foshan, CN
Contact	Wen Huang
510(k) history	1 submissions · 1 cleared · 2020-2020

REGULATORY CONSULTANT

Consulting firm	Guangzhou GLOMED Biological Technology Co., Ltd.
Contact	Cassie 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/k181691/>; 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 June 28, 2026