

K221548 Dental Air Polishing HandpieceSep 28, 2022
124 days to decisionK221548 · Product code: **EFB** · Dental
Source: <https://www.510kdatabase.net/k221548/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Handpiece, Air-powered, Dental (EFB)
Date received	May 27, 2022
Decision date	Sep 28, 2022
Days to decision	124 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Guilin Woodpecker Medical Instrument Co., Ltd.
Location	Flintville, TN, US
Contact	Xunxian Wu
510(k) history	14 submissions · 14 cleared · 2006-2025

REGULATORY CONSULTANT

Consulting firm	Irc
Contact	Charles Mack

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/k221548/> 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 25, 2026