

K203615 Dental Scaler and Air PolisherDec 10, 2021
365 days to decisionK203615 · Product code: **ELC** · Dental
Source: <https://www.510kdatabase.net/k203615/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Scaler, Ultrasonic (ELC)
Date received	Dec 10, 2020
Decision date	Dec 10, 2021
Days to decision	365 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	Yiwei Wang
510(k) history	14 submissions · 14 cleared · 2006-2025

REGULATORY CONSULTANT

Consulting firm	Shenzhen Joyantech Consulting Co., Ltd.
Contact	Sonya Lai

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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