

**K230641 Ultrasonic Scaler Tips**Nov 21, 2023  
258 days to decisionK230641 · Product code: **ELC** · Dental  
Source: <https://www.510kdatabase.net/k230641/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Scaler, Ultrasonic (ELC)
Date received	Mar 8, 2023
Decision date	Nov 21, 2023
Days to decision	258 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Guilin Refine Medical Instrument Co., Ltd.</b>
Location	Guangxi, CN
Contact	Chen Judong
510(k) history	3 submissions · 3 cleared · 2023-2026

**REGULATORY CONSULTANT**

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Consulting firm	<b>Chonconn Medical Device Consulting Co., Ltd.</b>
Contact	Alice Yang

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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