

K240801 BioSonic US200 Ultrasonic Scaler (60034537)Jul 1, 2024
98 days to decisionK240801 · Product code: **ELC** · DentalSource: <https://www.510kdatabase.net/k240801/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Scaler, Ultrasonic (ELC)
Date received	Mar 25, 2024
Decision date	Jul 1, 2024
Days to decision	98 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Dent4you AG
Location	Heerbrugg, CH
Contact	Tricia Cregger
510(k) history	4 submissions · 4 cleared · 2022-2025

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k240801/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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