

K233844 OdneCleanAug 8, 2024
248 days to decisionK233844 · Product code: **ELC** · DentalSource: <https://www.510kdatabase.net/k233844/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Scaler, Ultrasonic (ELC)
Date received	Dec 4, 2023
Decision date	Aug 8, 2024
Days to decision	248 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Ogne AG
Location	D?bendorf, CH
Contact	Mark Bispinghoff
510(k) history	1 submissions · 1 cleared · 2024-2024

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k233844/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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