

K231391 Combi TouchMay 15, 2023
3 days to decisionK231391 · Product code: **ELC** · Dental
Source: <https://www.510kdatabase.net/k231391/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Scaler, Ultrasonic (ELC)
Date received	May 12, 2023
Decision date	May 15, 2023
Days to decision	3 days
Third-party review	Yes
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Mectron S.P.A.
Location	Carasco, IT
Contact	Edoardo Tronchet
510(k) history	13 submissions · 13 cleared · 2009-2025

REGULATORY CONSULTANT

Consulting firm	Regulatory Technology Services, LLC
Contact	Prithul Bom

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: FDA accessdata.fda.gov

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