

K251196 Composite Orthodontic Brackets and ButtonsApr 21, 2025
4 days to decisionK251196 · Product code: **DYW** · Dental
Source: <https://www.510kdatabase.net/k251196/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Bracket, Plastic, Orthodontic (DYW)
Date received	Apr 17, 2025
Decision date	Apr 21, 2025
Days to decision	4 days
Third-party review	Yes
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Ec Certification Service GmbH
Location	Sankt Veit An Der Glan, AT
Contact	Elisabeth Moschik
510(k) history	1 submissions · 1 cleared · 2025-2025

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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