

K211804 3Delta CrownDec 6, 2021
178 days to decisionK211804 · Product code: **EBF** · Dental
Source: <https://www.510kdatabase.net/k211804/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Material, Tooth Shade, Resin (EBF)
Date received	Jun 11, 2021
Decision date	Dec 6, 2021
Days to decision	178 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Statement

APPLICANT

Company	Deltamed GmbH
Location	Friedberg, DE
Contact	Michael Zimmermann
510(k) history	6 submissions · 6 cleared · 2011-2024

REGULATORY CONSULTANT

Consulting firm	Cosmedent, Inc.
Contact	Gary Chuyen

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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