

K212541 3Delta Denture Base - 3Delta Denture Bond - 3Delta Denture FixJan 10, 2022
151 days to decisionK212541 · Product code: **EBI** · Dental
Source: <https://www.510kdatabase.net/k212541/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Resin, Denture, Relining, Repairing, Rebasing (EBI)
Date received	Aug 12, 2021
Decision date	Jan 10, 2022
Days to decision	151 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)510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k212541/>; Data sourced from FDA 510(k) public records (accessdata.fda.gov).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at accessdata.fda.gov. - Generated May 26, 2026