

K230341 ACRIFIXApr 6, 2023
57 days to decisionK230341 · Product code: **EBI** · DentalSource: <https://www.510kdatabase.net/k230341/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Resin, Denture, Relining, Repairing, Rebasing (EBI)
Date received	Feb 8, 2023
Decision date	Apr 6, 2023
Days to decision	57 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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k230341/> 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