FDA 510(k) Premarket Notification

K230341 ACRIFIX

CLEARED

Apr 6, 2023
57 days to decision

K230341 · Product code: **EBI** · Dental
Source: 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