

K211854 VITA Akzent LCNov 22, 2021
159 days to decisionK211854 · Product code: **EBD** · Dental
Source: <https://www.510kdatabase.net/k211854/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Coating, Filling Material, Resin (EBD)
Date received	Jun 16, 2021
Decision date	Nov 22, 2021
Days to decision	159 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Vita Zahnfabrik GmbH H Rauter & CO
Location	Bad Sackingen, DE
Contact	Bernd Walker
510(k) history	3 submissions · 3 cleared · 2020-2021

REGULATORY CONSULTANT

Consulting firm	Vita North America
Contact	Lindsay Tilton

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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