

K191843 Ceramill A-TempOct 4, 2019
87 days to decisionK191843 · Product code: **EBG** · Dental
Source: <https://www.510kdatabase.net/k191843/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Crown And Bridge, Temporary, Resin (EBG)
Date received	Jul 9, 2019
Decision date	Oct 4, 2019
Days to decision	87 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Amann Girrback AG
Location	Koblach, AT
Contact	Debora Engel
510(k) history	3 submissions · 3 cleared · 2017-2019

REGULATORY CONSULTANT

Consulting firm	Emergo Europe Consulting
Contact	Rachel Paul

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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