

K211101 E-TempJun 14, 2021
62 days to decisionK211101 · Product code: **EBG** · Dental
Source: <https://www.510kdatabase.net/k211101/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Crown And Bridge, Temporary, Resin (EBG)
Date received	Apr 13, 2021
Decision date	Jun 14, 2021
Days to decision	62 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Envisontec GmbH
Location	Gladbeck, DE
Contact	Ruediger van Bernum
510(k) history	5 submissions · 5 cleared · 2020-2022

REGULATORY CONSULTANT

Consulting firm	Qserve Group, Us, Inc.
Contact	Patsy J. Trisler

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: FDA accessdata.fda.gov

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