

K200273 FREEPRINT tempOct 27, 2020
266 days to decisionK200273 · Product code: **EBG** · Dental
Source: <https://www.510kdatabase.net/k200273/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Crown And Bridge, Temporary, Resin (EBG)
Date received	Feb 4, 2020
Decision date	Oct 27, 2020
Days to decision	266 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Detax GmbH & Co. KG
Location	Amsterdam, NL
Contact	Markus Stratmann
510(k) history	5 submissions · 5 cleared · 2000-2020

REGULATORY CONSULTANT

Consulting firm	Qserve Consultancy B.V.
Contact	Jan-Paul Van Loon

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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k200273/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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