

**K222877 FREEPRINT crown**Sep 23, 2022  
1 days to decisionK222877 · Product code: **EBF** · DentalSource: <https://www.510kdatabase.net/k222877/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Material, Tooth Shade, Resin (EBF)
Date received	Sep 22, 2022
Decision date	Sep 23, 2022
Days to decision	1 days
Third-party review	Yes
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Detax GmbH</b>
Location	Ettingen, DE
Contact	Markus Stratmann
510(k) history	3 submissions · 3 cleared · 2022-2025

**REGULATORY CONSULTANT**

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Consulting firm	<b>Regulatory Technology Services, LLC</b>
Contact	Prithul Bom

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

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Device record: <https://www.510kdatabase.net/k222877/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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