

**K200461 Freeprint denture**Nov 16, 2020  
265 days to decisionK200461 · Product code: **EBI** · DentalSource: <https://www.510kdatabase.net/k200461/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Resin, Denture, Relining, Repairing, Rebasing (EBI)
Date received	Feb 25, 2020
Decision date	Nov 16, 2020
Days to decision	265 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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

**REGULATORY CONSULTANT**

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Consulting firm	<b>Qserve Consultancy B.V.</b>
Contact	Jan-Paul van Loon

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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