

**K221022 NextDent Ortho Flex**Oct 21, 2022  
198 days to decisionK221022 · Product code: **MQC** · Dental  
Source: <https://www.510kdatabase.net/k221022/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Abbreviated
Device classification	Mouthguard, Prescription (MQC)
Date received	Apr 6, 2022
Decision date	Oct 21, 2022
Days to decision	198 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Vertex-Dental B.V.</b>
Location	Claremont, NH, US
Contact	Connie Peterse-van der Koppel
510(k) history	8 submissions · 8 cleared · 2010-2024

**REGULATORY CONSULTANT**

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Consulting firm	<b>Qserve Group, Us, Inc.</b>
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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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k221022/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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