

**K212961 SMILERS**Sep 20, 2021  
4 days to decisionK212961 · Product code: **NXC** · Dental  
Source: <https://www.510kdatabase.net/k212961/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Aligner, Sequential (NXC)
Date received	Sep 16, 2021
Decision date	Sep 20, 2021
Days to decision	4 days
Third-party review	Yes
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Biotech Dental Smilers, Sas</b>
Location	Salon De Provence, FR
Contact	Delphine Mercier
510(k) history	1 submissions · 1 cleared · 2021-2021

**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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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k212961/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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