

**K191774 SmileAlign Orthodontic Aligner System**Sep 30, 2019  
90 days to decisionK191774 · Product code: **NXC** · Dental  
Source: <https://www.510kdatabase.net/k191774/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Aligner, Sequential (NXC)
Date received	Jul 2, 2019
Decision date	Sep 30, 2019
Days to decision	90 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>3D Global Biotech, Inc.</b>
Location	New Taipei City 221, TW
Contact	Keng-Liang Ou
510(k) history	2 submissions · 2 cleared · 2019-2022

**REGULATORY CONSULTANT**

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Consulting firm	<b>Duocare, LLC</b>
Contact	Diana Lam

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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