

**K210349 TKO Composite Bite Turbo Gel**Jul 20, 2021  
162 days to decisionK210349 · Product code: **EBF** · Dental  
Source: <https://www.510kdatabase.net/k210349/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Material, Tooth Shade, Resin (EBF)
Date received	Feb 8, 2021
Decision date	Jul 20, 2021
Days to decision	162 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Reliance Orthodontic Products, Inc.</b>
Location	Itasca, IL, US
Contact	Christine Cook
510(k) history	32 submissions · 32 cleared · 1988-2021

**REGULATORY CONSULTANT**

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Consulting firm	<b>Cook Device Solutions</b>
Contact	Brian Dean

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: [FDA accessdata.fda.gov](https://accessdata.fda.gov)510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k210349/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](https://accessdata.fda.gov)).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at [accessdata.fda.gov](https://accessdata.fda.gov). - Generated May 13, 2026