

**K222549 OpenTex**May 11, 2023  
261 days to decisionK222549 · Product code: **NPK** · Dental  
Source: <https://www.510kdatabase.net/k222549/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Barrier, Synthetic, Intraoral (NPK)
Date received	Aug 23, 2022
Decision date	May 11, 2023
Days to decision	261 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Purgo Biologics, Inc.</b>
Location	Seongnam-Si, KR
Contact	Byungsun Kim
510(k) history	6 submissions · 6 cleared · 2018-2024

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k222549/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://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](http://accessdata.fda.gov). - Generated May 26, 2026