

**K191737 The Graft Bone Substitute**Feb 14, 2020  
231 days to decisionK191737 · Product code: **NPM** · Dental  
Source: <https://www.510kdatabase.net/k191737/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Bone Grafting Material, Animal Source (NPM)
Date received	Jun 28, 2019
Decision date	Feb 14, 2020
Days to decision	231 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Purgo Biologics, Inc.</b>
Location	Seongnam-Si, KR
Contact	Eun Ho 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/k191737/> 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