

**K191992 PELNAC Bilayer Wound Matrix**Apr 29, 2020  
279 days to decisionK191992 · Product code: **KGN** · General & Plastic SurgerySource: <https://www.510kdatabase.net/k191992/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Wound Dressing With Animal-derived Material(s) (KGN)
Date received	Jul 25, 2019
Decision date	Apr 29, 2020
Days to decision	279 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Gunze Limited</b>
Location	Ayabe, Kyoto, JP
Contact	Hidenori Nishioka
510(k) history	5 submissions · 5 cleared · 2013-2022

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k191992/> 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