

**K213231 Kerecis Silicone**Jun 29, 2022  
272 days to decisionK213231 · Product code: **KGN** · General & Plastic SurgerySource: <https://www.510kdatabase.net/k213231/>**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	Sep 30, 2021
Decision date	Jun 29, 2022
Days to decision	272 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Kerecis Limited</b>
Location	Isafjordur, IS
Contact	Gudmundur Fertram Sigurjonsson
510(k) history	10 submissions · 10 cleared · 2013-2025

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k213231/> 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