

**K190528 MariGen Wound Extra**Jul 10, 2019  
128 days to decisionK190528 · Product code: **KGN** · General & Plastic SurgerySource: <https://www.510kdatabase.net/k190528/>**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	Mar 4, 2019
Decision date	Jul 10, 2019
Days to decision	128 days
Third-party review	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/k190528/> 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