

K251845 Marigen Wound ExtraJul 16, 2025
30 days to decisionK251845 · Product code: **KGN** · General & Plastic SurgerySource: <https://www.510kdatabase.net/k251845/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Wound Dressing With Animal-derived Material(s) (KGN)
Date received	Jun 16, 2025
Decision date	Jul 16, 2025
Days to decision	30 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary
Other names	Kerecis Silicone; Kerecis Parvus

APPLICANT

Company	Kerecis Limited
Location	Isafjordur, IS
Contact	Skuli Magnusson
510(k) history	10 submissions · 10 cleared · 2013-2025

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