

K192346 scaffolene CL100 Bioresorbable Collagen MatrixFeb 28, 2020
183 days to decisionK192346 · Product code: **KGN** · General & Plastic Surgery
Source: <https://www.510kdatabase.net/k192346/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Wound Dressing With Animal-derived Material(s) (KGN)
Date received	Aug 29, 2019
Decision date	Feb 28, 2020
Days to decision	183 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Freudenberg Technology Innovation SE & Co. KG
Location	Weinheim, DE
Contact	Denis Reibel
510(k) history	1 submissions · 1 cleared · 2020-2020

REGULATORY CONSULTANT

Consulting firm	Parexel International
Contact	Sugato De

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: [FDA accessdata.fda.gov](https://accessdata.fda.gov)

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