

K213498 PELNAC Meshed Bilayer Wound MatrixJul 14, 2022
255 days to decisionK213498 · Product code: **KG**N · General & Plastic Surgery
Source: <https://www.510kdatabase.net/k213498/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Wound Dressing With Animal-derived Material(s) (KGN)
Date received	Nov 1, 2021
Decision date	Jul 14, 2022
Days to decision	255 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

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

REGULATORY CONSULTANT

Consulting firm	Emergo Global Consulting, LLC
Contact	Stuart R Goldman

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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