

K260669 Endoform Dermal Template

Jun 24, 2026
114 days to decision

K260669 · Product code: **KGN** · General & Plastic Surgery
Source: <https://www.510kdatabase.net/k260669/>

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Wound Dressing With Animal-derived Material(s) (KGN)
Date received	Mar 2, 2026
Decision date	Jun 24, 2026
Days to decision	114 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Aroa Biosurgery , Ltd.
Location	Airport Oaks, NZ
Contact	Thanh Minh Lam
Website	https://aroa.com/
510(k) history	8 submissions · 8 cleared · 2018-2026

Aroa Biosurgery, Ltd. is a medical device company specializing in soft tissue repair and regenerative healing products. The company operates with a manufacturing facility in Airport Oaks, New Zealand, and develops bioscaffold-based solutions for wound management and surgical reconstruction. Aroa Biosurgery has received FDA 510(k) clearances from total submissions since its first clearance in 2018. The company's portfolio is dominated by General & Plastic Surgery devices, which account for 86% of submissions. The most recent clearance was issued in 2025, confirming the com...