

K250598 Endoform Reconstructive Template - PLGAJun 3, 2025
95 days to decisionK250598 · Product code: **FTM** · General & Plastic Surgery
Source: <https://www.510kdatabase.net/k250598/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Mesh, Surgical (FTM)
Date received	Feb 28, 2025
Decision date	Jun 3, 2025
Days to decision	95 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Aroa Biosurgery , Ltd.
Location	Airport Oaks, NZ
Contact	Stacy Spies
Website	https://aroa.com/
510(k) history	7 submissions · 7 cleared · 2018-2025

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...