

K183398 Endoform RestellaApr 11, 2019
125 days to decisionK183398 · Product code: **FTM** · General & Plastic Surgery
Source: <https://www.510kdatabase.net/k183398/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Mesh, Surgical (FTM)
Date received	Dec 7, 2018
Decision date	Apr 11, 2019
Days to decision	125 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Aroa Biosurgery , Ltd.
Location	Airport Oaks, NZ
Contact	Tina O'Brien
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...
