

K223373 Enivo™Apr 7, 2023
154 days to decisionK223373 · Product code: **BTA** · General & Plastic SurgerySource: <https://www.510kdatabase.net/k223373/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Pump, Portable, Aspiration (manual Or Powered) (BTA)
Date received	Nov 4, 2022
Decision date	Apr 7, 2023
Days to decision	154 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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