

K162461 Endoform Plastics and Reconstructive MatrixDec 20, 2016
109 days to decisionK162461 · Product code: **FTM** · General & Plastic SurgerySource: <https://www.510kdatabase.net/k162461/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Mesh, Surgical (FTM)
Date received	Sep 2, 2016
Decision date	Dec 20, 2016
Days to decision	109 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Aroa Biosurgery (Formerly Mesynthes Limited)
Location	Auckland, NZ
Contact	Yasmin Rai
510(k) history	1 submissions · 1 cleared · 2016-2016

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