

K153633 Endoform Reconstructive TemplateMar 15, 2016
88 days to decisionK153633 · Product code: **FTM** · General & Plastic SurgerySource: <https://www.510kdatabase.net/k153633/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Mesh, Surgical (FTM)
Date received	Dec 18, 2015
Decision date	Mar 15, 2016
Days to decision	88 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Aroa Biosurgery Limited (Formerly Mesynthes Limited)
Location	Auckland, NZ
Contact	Yasmin Rai
510(k) history	2 submissions · 2 cleared · 2016-2016

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