

**K203600 VersaWrap**Mar 9, 2021  
90 days to decisionK203600 · Product code: **FTM** · General & Plastic SurgerySource: <https://www.510kdatabase.net/k203600/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Mesh, Surgical (FTM)
Date received	Dec 9, 2020
Decision date	Mar 9, 2021
Days to decision	90 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Alafair Biosciences, Inc.</b>
Location	Austin, TX, US
Contact	Angela Mallery
510(k) history	7 submissions · 7 cleared · 2016-2024

**REGULATORY CONSULTANT**

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Consulting firm	<b>Namsa</b>
Contact	Angela Mallery

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: [FDA accessdata.fda.gov](https://accessdata.fda.gov)

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