

K213163 VersaWrapOct 29, 2021
31 days to decisionK213163 · Product code: **FTM** · General & Plastic SurgerySource: <https://www.510kdatabase.net/k213163/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Mesh, Surgical (FTM)
Date received	Sep 28, 2021
Decision date	Oct 29, 2021
Days to decision	31 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k213163/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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