

K240817 VersaWrapJun 14, 2024
81 days to decisionK240817 · Product code: **OWW** · Orthopedic
Source: <https://www.510kdatabase.net/k240817/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Mesh, Surgical, Absorbable, Orthopaedics, Reinforcement Of Tendon (OWW)
Date received	Mar 25, 2024
Decision date	Jun 14, 2024
Days to decision	81 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k240817/>; Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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