

K251655 VersaCoat Tendon Protector (VTP-44G2)Jul 18, 2025
49 days to decisionK251655 · Product code: **OWW** · Orthopedic
Source: <https://www.510kdatabase.net/k251655/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Mesh, Surgical, Absorbable, Orthopaedics, Reinforcement Of Tendon (OWW)
Date received	May 30, 2025
Decision date	Jul 18, 2025
Days to decision	49 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary
Other names	VersaCoat Tendon Protector (VTP-12G1)

APPLICANT

Company	Alafair Biosciences
Location	Austin, TX, US
Contact	Sarah Mayes
510(k) history	3 submissions · 3 cleared · 2025-2025

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