

K212306 Tapestry Biointegrative ImplantNov 2, 2021
102 days to decisionK212306 · Product code: **OWY** · Orthopedic
Source: <https://www.510kdatabase.net/k212306/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Mesh, Surgical, Collagen, Orthopaedics, Reinforcement Of Tendon (OWY)
Date received	Jul 23, 2021
Decision date	Nov 2, 2021
Days to decision	102 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Embodiment, Inc.
Location	Norfolk, VA, US
Contact	Brianna Schehr
510(k) history	6 submissions · 6 cleared · 2020-2025

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k212306/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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