

K243843 Tendon Protect (50242)Jun 4, 2025
173 days to decisionK243843 · Product code: **OWY** · Orthopedic
Source: <https://www.510kdatabase.net/k243843/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Mesh, Surgical, Collagen, Orthopaedics, Reinforcement Of Tendon (OWY)
Date received	Dec 13, 2024
Decision date	Jun 4, 2025
Days to decision	173 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Kerecis Limited
Location	Isafjordur, IS
Contact	Skuli Magnusson
510(k) history	10 submissions · 10 cleared · 2013-2025

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k243843/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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