

K222501 Regeneten Bioinductive ImplantMay 11, 2023
266 days to decisionK222501 · Product code: **OWY** · Orthopedic
Source: <https://www.510kdatabase.net/k222501/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Mesh, Surgical, Collagen, Orthopaedics, Reinforcement Of Tendon (OWY)
Date received	Aug 18, 2022
Decision date	May 11, 2023
Days to decision	266 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Smith and Nephew, Inc.
Location	Andover, MA, US
Contact	Jenna Horsley
510(k) history	7 submissions · 7 cleared · 2016-2023

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