

**K242631 REGENETEN™ Bioinductive Implant**Nov 26, 2024  
84 days to decisionK242631 · Product code: **OWY** · Orthopedic  
Source: <https://www.510kdatabase.net/k242631/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Mesh, Surgical, Collagen, Orthopaedics, Reinforcement Of Tendon (OWY)
Date received	Sep 3, 2024
Decision date	Nov 26, 2024
Days to decision	84 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Smith &amp; Nephew Inc., Endoscopy Div.</b>
Location	Andover, MA, US
Contact	Lacey Klungseth
510(k) history	10 submissions · 10 cleared · 2007-2024

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k242631/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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