FDA 510(k) Premarket Notification

K242631 REGENETEN™ Bioinductive Implant

CLEARED

Nov 26, 2024
84 days to decision

K242631 · Product code: **OWY** · Orthopedic
Source: https://www.510kdatabase.net/k242631/

SUBMISSION DETAILS

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

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