

K250997 Integrity™ ImplantJun 17, 2025
77 days to decisionK250997 · Product code: **OWX** · Orthopedic
Source: <https://www.510kdatabase.net/k250997/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Mesh, Surgical, Non-absorbable, Orthopaedics, Reinforcement Of Tendon (OWX)
Date received	Apr 1, 2025
Decision date	Jun 17, 2025
Days to decision	77 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Anika Therapeutics, Inc.
Location	Bedford, MA, US
Contact	Shajunath Nirupama
Website	http://www.anikatherapeutics.com/
510(k) history	9 submissions · 9 cleared · 2017-2025

Anika Therapeutics, Inc. is a global leader in hyaluronic acid-based orthopedic regenerative solutions and osteoarthritis pain management. The company develops advanced tissue repair, cartilage regeneration, and injectable bone substitute technologies with a manufacturing facility in Bedford, US. Anika has received FDA 510(k) clearances from total submissions since 2017. Orthopedic devices represent the dominant focus of the company's regulatory portfolio. The latest clearance was received in 2025, reflecting active ongoing innovation and market engagement. The company's ...