FDA 510(k) Premarket Notification

CLEARED

K222487 Anika Tissue Tack Fixation System

May 8, 2023
264 days to decision

K222487 · Product code: **GDW** · General & Plastic Surgery
Source: https://www.510kdatabase.net/k222487/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Staple, Implantable (GDW)
Date received	Aug 17, 2022
Decision date	May 8, 2023
Days to decision	264 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Anika Therapeutics, Inc.**
Location	Beford, 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 ...

510k Database - www.510kdatabase.net
Device record: https://www.510kdatabase.net/k222487/ Data sourced from FDA 510(k) public records (accessdata.fda.gov).
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