

K223860 Integrity™ Bone Staple Fixation SystemMay 22, 2023
150 days to decisionK223860 · Product code: **MBI** · Orthopedic
Source: <https://www.510kdatabase.net/k223860/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Fastener, Fixation, Nondegradable, Soft Tissue (MBI)
Date received	Dec 23, 2022
Decision date	May 22, 2023
Days to decision	150 days
Third-party review	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 ...
