

K251750 Trax EX AnchorMar 12, 2026
276 days to decisionK251750 · Product code: **MBI** · Orthopedic
Source: <https://www.510kdatabase.net/k251750/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Fastener, Fixation, Nondegradable, Soft Tissue (MBI)
Date received	Jun 9, 2025
Decision date	Mar 12, 2026
Days to decision	276 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Trax Surgical, Inc.
Location	Stoughton, MA, US
Contact	Shalain Siddiqui
Website	https://www.traxsurgical.com
510(k) history	1 submissions · 1 cleared · 2026-2026

Trax Surgical, Inc. manufactures bone compression tools and surgical instrumentation for extremity procedures. The company specializes in headed and headless compression bone screws, snap-away bone screws, instrumentation kits, and nitinol compression staples. Operations are based in Stoughton, Massachusetts, at an FDA-registered facility certified to ISO 13485:2016. Trax Surgical has received FDA 510(k) clearance from total submission. The company's focus is entirely on Orthopedic devices for internal fixation, reconstruction, and fracture repair. The most recent clearan...