FDA 510(k) Premarket Notification

K250095 All-Suture Dual Anchor System

CLEARED

Sep 5, 2025
234 days to decision

K250095 · Product code: **MBI** · Orthopedic
Source: https://www.510kdatabase.net/k250095/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Fastener, Fixation, Nondegradable, Soft Tissue (MBI)
Date received	Jan 14, 2025
Decision date	Sep 5, 2025
Days to decision	234 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Suturetech, Inc.**
Location	Durham, NC, US
Contact	Benjamin Arnold
510(k) history	1 submissions · 1 cleared · 2025-2025