FDA 510(k) Premarket Notification

K252961 Fusion FibFix Nail

CLEARED

Mar 18, 2026
183 days to decision

K252961 · Product code: **HSB** · Orthopedic
Source: https://www.510kdatabase.net/k252961/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Rod, Fixation, Intramedullary And Accessories (HSB)
Date received	Sep 16, 2025
Decision date	Mar 18, 2026
Days to decision	183 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Fusion Orthopedics USA, LLC**
Location	Mesa, AZ, US
Contact	Catalina Pardo
Website	https://fusionorthopedics.com
510(k) history	1 submissions · 1 cleared · 2026-2026

Fusion Orthopedics USA, LLC designs and manufactures orthopedic surgical implants and fixation systems. The company operates with a manufacturing facility in Mesa, US. The company has received FDA 510(k) clearance from total submission. Its regulatory activity spans 2026, with focus on orthopedic device development. The FibFix Nail System, a low-profile intramedullary nail for fibula fractures and osteotomies, represents the company's cleared portfolio. Fusion Orthopedics offers a broad range of orthopedic solutions including bunion correction systems, syndesmotic fixatio...