FDA 510(k) Premarket Notification

K240288 SF Push- in Anchor

CLEARED

Apr 1, 2024
60 days to decision

K240288 · Product code: **MAI** · Orthopedic
Source: https://www.510kdatabase.net/k240288/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Fastener, Fixation, Biodegradable, Soft Tissue (MAI)
Date received	Feb 1, 2024
Decision date	Apr 1, 2024
Days to decision	60 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Surgical Fusion Technologies GmbH**
Location	Schlieren, CH
Contact	Joerg Mayer
510(k) history	2 submissions · 2 cleared · 2024-2026

REGULATORY CONSULTANT

Consulting firm	**Hogan Lovells US LLP**
Contact	Payne Kelli

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: FDA accessdata.fda.gov