FDA 510(k) Premarket Notification

K253618 QuadLock™ Fixation System

CLEARED

Jan 6, 2026
49 days to decision

K253618 · Product code: **MBI** · Orthopedic
Source: https://www.510kdatabase.net/k253618/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Fastener, Fixation, Nondegradable, Soft Tissue (MBI)
Date received	Nov 18, 2025
Decision date	Jan 6, 2026
Days to decision	49 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Abanza Tecnomed S.L**
Location	Mutilva, ES
Contact	Andrea Larranaga
510(k) history	4 submissions · 4 cleared · 2022-2026

REGULATORY CONSULTANT

Consulting firm	**Precision Life Science Partners**
Contact	Jessica Czamanski

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