

K243712 WasherCap™ Mini Fixation System (Model 45)Jan 30, 2025
59 days to decisionK243712 · Product code: **MBI** · Orthopedic
Source: <https://www.510kdatabase.net/k243712/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Fastener, Fixation, Nondegradable, Soft Tissue (MBI)
Date received	Dec 2, 2024
Decision date	Jan 30, 2025
Days to decision	59 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

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

REGULATORY CONSULTANT

Consulting firm	Presicion 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](https://accessdata.fda.gov)510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k243712/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at accessdata.fda.gov. - Generated May 13, 2026