

K212197 WasherCap Fixation SystemSep 22, 2022
435 days to decisionK212197 · Product code: **MBI** · Orthopedic
Source: <https://www.510kdatabase.net/k212197/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Fastener, Fixation, Nondegradable, Soft Tissue (MBI)
Date received	Jul 14, 2021
Decision date	Sep 22, 2022
Days to decision	435 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k212197/> 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 26, 2026