

K230507 Zimed Distal Medial Tibial Plate and Screw SystemJan 4, 2024
314 days to decisionK230507 · Product code: **HWC** · Orthopedic
Source: <https://www.510kdatabase.net/k230507/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Screw, Fixation, Bone (HWC)
Date received	Feb 24, 2023
Decision date	Jan 4, 2024
Days to decision	314 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Zimed Medikal
Location	Gaziantep, TR
Contact	H.Nurcan Bilgi
510(k) history	1 submissions · 1 cleared · 2024-2024

REGULATORY CONSULTANT

Consulting firm	RQMIS, Inc.
Contact	Barry E. Sands

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/k230507/> 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