

K213036 Treace Medical Concepts (TMC) Screw Fixation SystemOct 21, 2021
30 days to decisionK213036 · Product code: **HWC** · Orthopedic
Source: <https://www.510kdatabase.net/k213036/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Screw, Fixation, Bone (HWC)
Date received	Sep 21, 2021
Decision date	Oct 21, 2021
Days to decision	30 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Treace Medical Concepts, Inc.
Location	Ponte Vedra, FL, US
Contact	Kristina Hall
510(k) history	15 submissions · 15 cleared · 2015-2026

REGULATORY CONSULTANT

Consulting firm	MRC Global, LLC
Contact	Danielle Besal

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/k213036/> 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