

K260361 Treace Medical Concepts (TMC) Screw Fixation SystemMar 6, 2026
30 days to decisionK260361 · Product code: **HWC** · Orthopedic
Source: <https://www.510kdatabase.net/k260361/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Screw, Fixation, Bone (HWC)
Date received	Feb 4, 2026
Decision date	Mar 6, 2026
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	Melissa Coloroso
510(k) history	15 submissions · 15 cleared · 2015-2026

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