

K251135 Treace Medical Concepts (TMC) Implant Fixation SystemAug 21, 2025
129 days to decisionK251135 · Product code: **HRS** · Orthopedic
Source: <https://www.510kdatabase.net/k251135/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Plate, Fixation, Bone (HRS)
Date received	Apr 14, 2025
Decision date	Aug 21, 2025
Days to decision	129 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Treace Medical Concepts
Location	Ponte Vedra, FL, US
Contact	Brittany Grochala
510(k) history	5 submissions · 5 cleared · 2022-2025

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