

K183321 Treace Medical Concepts (TMC) Plating SystemJan 25, 2019
56 days to decisionK183321 · Product code: **HRS** · Orthopedic
Source: <https://www.510kdatabase.net/k183321/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Plate, Fixation, Bone (HRS)
Date received	Nov 30, 2018
Decision date	Jan 25, 2019
Days to decision	56 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	Rachel Osbeck
510(k) history	15 submissions · 15 cleared · 2015-2026

REGULATORY CONSULTANT

Consulting firm	Memphis Regulatory Consulting, LLC
Contact	Dawn Norman

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: FDA accessdata.fda.gov

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