

**K200961 Treace Medical Concepts (TMC) Plating System**May 8, 2020  
28 days to decisionK200961 · Product code: **HRS** · Orthopedic  
Source: <https://www.510kdatabase.net/k200961/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Plate, Fixation, Bone (HRS)
Date received	Apr 10, 2020
Decision date	May 8, 2020
Days to decision	28 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Treace Medical Concepts, Inc.</b>
Location	Ponte Vedra, FL, US
Contact	Rachel Osbeck
510(k) history	15 submissions · 15 cleared · 2015-2026

**REGULATORY CONSULTANT**

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Consulting firm	<b>MRC Global</b>
Contact	Danielle Besal

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

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k200961/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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