

**K234059 Forma Medical Optimal Plating System**Jun 26, 2024  
187 days to decisionK234059 · Product code: **HRS** · Orthopedic  
Source: <https://www.510kdatabase.net/k234059/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Plate, Fixation, Bone (HRS)
Date received	Dec 22, 2023
Decision date	Jun 26, 2024
Days to decision	187 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Forma Medical, Inc.</b>
Location	Camp Hill, PA, US
Contact	James Gault
510(k) history	2 submissions · 2 cleared · 2023-2024

**REGULATORY CONSULTANT**

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Consulting firm	<b>Jalex Medical, LLC</b>
Contact	Jennifer Palinchik

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

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