

**K240388 Osteotomy Truss System (OTS)**Nov 1, 2024  
267 days to decisionK240388 · Product code: **HRS** · Orthopedic  
Source: <https://www.510kdatabase.net/k240388/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Plate, Fixation, Bone (HRS)
Date received	Feb 8, 2024
Decision date	Nov 1, 2024
Days to decision	267 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>4Web Medical, Inc.</b>
Location	Frisco, TX, US
Contact	Jonathan Hires
510(k) history	11 submissions · 11 cleared · 2021-2025

**REGULATORY CONSULTANT**

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Consulting firm	<b>Silver Pine Consulting</b>
Contact	Richard Jansen

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/k240388/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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