

**K183363 Treace Medical Concepts (TMC) Snap-Off Screw System**Jun 13, 2019  
191 days to decisionK183363 · Product code: **HWC** · Orthopedic  
Source: <https://www.510kdatabase.net/k183363/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Screw, Fixation, Bone (HWC)
Date received	Dec 4, 2018
Decision date	Jun 13, 2019
Days to decision	191 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-X, LLC</b>
Contact	Dawn Norman

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: [FDA accessdata.fda.gov](https://accessdata.fda.gov)510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k183363/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](https://accessdata.fda.gov)).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at [accessdata.fda.gov](https://accessdata.fda.gov). - Generated June 28, 2026