

**K150443 ToeTac Hammertoe Fixation System**Jun 4, 2015  
104 days to decisionK150443 · Product code: **HWC** · Orthopedic  
Source: <https://www.510kdatabase.net/k150443/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Screw, Fixation, Bone (HWC)
Date received	Feb 20, 2015
Decision date	Jun 4, 2015
Days to decision	104 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Restore Surgical, LLC Db a Instratek</b>
Location	Houston, TX, US
Contact	JEFF SEAVEY
510(k) history	3 submissions · 3 cleared · 2015-2017

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k150443/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://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](http://accessdata.fda.gov). - Generated May 16, 2026