

**K071541 SBI TWISTOFIX**Sep 10, 2007  
97 days to decisionK071541 · Product code: **HWC** · Orthopedic  
Source: <https://www.510kdatabase.net/k071541/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Screw, Fixation, Bone (HWC)
Date received	Jun 5, 2007
Decision date	Sep 10, 2007
Days to decision	97 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Small Bone Innovations, Inc.</b>
Location	New York, NY, US
Contact	ROBERT HOEHN
510(k) history	20 submissions · 20 cleared · 2006-2013

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k071541/> 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 18, 2026