

**K142052 ORTHOFIX GALAXY UNYCO DIAPHYSEAL TIBIA KIT**Dec 5, 2014  
130 days to decisionK142052 · Product code: **KTT** · Orthopedic  
Source: <https://www.510kdatabase.net/k142052/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Appliance, Fixation, Nail/blade/plate Combination, Multiple Component (KTT)
Date received	Jul 28, 2014
Decision date	Dec 5, 2014
Days to decision	130 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Orthofix Srl</b>
Location	Rockville, MD, US
Contact	CHERYL WAGONER
510(k) history	36 submissions · 36 cleared · 1995-2025

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k142052/> 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 17, 2026