

**K160830 Integra External Fixation System**Jul 6, 2016  
103 days to decisionK160830 · Product code: **KTT** · Orthopedic  
Source: <https://www.510kdatabase.net/k160830/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Appliance, Fixation, Nail/blade/plate Combination, Multiple Component (KTT)
Date received	Mar 25, 2016
Decision date	Jul 6, 2016
Days to decision	103 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Ascension Orthopedics</b>
Location	Austin, TX, US
Contact	Jayana Kenana
510(k) history	7 submissions · 7 cleared · 2014-2018

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k160830/> 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 June 28, 2026