

**K162241 TITAN 3-D™ Wedge System**Apr 3, 2017  
236 days to decisionK162241 · Product code: **PLF** · Orthopedic  
Source: <https://www.510kdatabase.net/k162241/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Bone Wedge (PLF)
Date received	Aug 10, 2016
Decision date	Apr 3, 2017
Days to decision	236 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Paragon 28</b>
Location	Chesterland, OH, US
Contact	Frank S. Bono
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/k162241/> 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