

**K191783 Parcus Synd-EZ Ti**Oct 9, 2019  
98 days to decisionK191783 · Product code: **MBI** · Orthopedic  
Source: <https://www.510kdatabase.net/k191783/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Fastener, Fixation, Nondegradable, Soft Tissue (MBI)
Date received	Jul 3, 2019
Decision date	Oct 9, 2019
Days to decision	98 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Parcus Medical, LLC</b>
Location	Sturgeon Bay, WI, US
Contact	Paul Vagts
510(k) history	28 submissions · 28 cleared · 2009-2022

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k191783/> 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 14, 2026