

**K183331 Parcus GFS BTB**Feb 7, 2019  
66 days to decisionK183331 · Product code: **MBI** · Orthopedic  
Source: <https://www.510kdatabase.net/k183331/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Fastener, Fixation, Nondegradable, Soft Tissue (MBI)
Date received	Dec 3, 2018
Decision date	Feb 7, 2019
Days to decision	66 days
Third-party review	No
Combination product	No
PCCP authorized	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/k183331/> 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