

**K212739 ActiFlip**Oct 6, 2021  
37 days to decisionK212739 · Product code: **MBI** · Orthopedic  
Source: <https://www.510kdatabase.net/k212739/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Fastener, Fixation, Nondegradable, Soft Tissue (MBI)
Date received	Aug 30, 2021
Decision date	Oct 6, 2021
Days to decision	37 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	Calen Souther
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/k212739/> 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 13, 2026