

**K162198 GFS Ultimate**Nov 18, 2016  
105 days to decisionK162198 · Product code: **MBI** · Orthopedic  
Source: <https://www.510kdatabase.net/k162198/>**SUBMISSION DETAILS**

---

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Fastener, Fixation, Nondegradable, Soft Tissue (MBI)
Date received	Aug 5, 2016
Decision date	Nov 18, 2016
Days to decision	105 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

---

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

---

510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k162198/> 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