

K183501 Parcus Twist AP Suture AnchorsMar 15, 2019
88 days to decisionK183501 · Product code: **MAI** · Orthopedic
Source: <https://www.510kdatabase.net/k183501/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Fastener, Fixation, Biodegradable, Soft Tissue (MAI)
Date received	Dec 17, 2018
Decision date	Mar 15, 2019
Days to decision	88 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k183501/> Data sourced from FDA 510(k) public records (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. - Generated June 28, 2026