

K232513 X-Twist Biocomposite Suture AnchorSep 18, 2023
31 days to decisionK232513 · Product code: **MAI** · Orthopedic
Source: <https://www.510kdatabase.net/k232513/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Fastener, Fixation, Biodegradable, Soft Tissue (MAI)
Date received	Aug 18, 2023
Decision date	Sep 18, 2023
Days to decision	31 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Parcus Medical
Location	Sarasota, FL, US
Contact	Calen Souther
510(k) history	3 submissions · 3 cleared · 2017-2023

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k232513/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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