

K231831 TiLink-L Joint Fusion SystemAug 3, 2023
42 days to decisionK231831 · Product code: **OUR** · Orthopedic
Source: <https://www.510kdatabase.net/k231831/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Sacroiliac Joint Fixation (OUR)
Date received	Jun 22, 2023
Decision date	Aug 3, 2023
Days to decision	42 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Surgentec
Location	Boca Raton, FL, US
Contact	Andrew Shoup
510(k) history	3 submissions · 3 cleared · 2020-2023

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k231831/> 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 May 27, 2026