

K230088 Ankle Truss System (ATS)Mar 21, 2024
434 days to decisionK230088 · Product code: **SAI** · Orthopedic
Source: <https://www.510kdatabase.net/k230088/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Ankle Fusion Cage (SAI)
Date received	Jan 12, 2023
Decision date	Mar 21, 2024
Days to decision	434 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	4Web Medical, Inc.
Location	Frisco, TX, US
Contact	Lewis Harrison
510(k) history	11 submissions · 11 cleared · 2021-2025

REGULATORY CONSULTANT

Consulting firm	DuVal & Associates, P.A.
Contact	Kathy Herzog

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: FDA accessdata.fda.gov

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