

**K212524 Anteralign Spinal System with Titan nanoLOCK
Surface Technology**Dec 8, 2021
119 days to decisionK212524 · Product code: **MAX** · Orthopedic
Source: <https://www.510kdatabase.net/k212524/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Intervertebral Fusion Device With Bone Graft, Lumbar (MAX)
Date received	Aug 11, 2021
Decision date	Dec 8, 2021
Days to decision	119 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Medtronic Sofamor Danek USA, Inc.
Location	Memphis, TN, US
Contact	Elizabeth Hamilton
510(k) history	170 submissions · 159 cleared · 2000-2026

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k212524/>. 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 13, 2026