

K214011 Catalyft™ PL Expandable Interbody System Navigated Instruments, Anteralign™ TL Spinal System with Titan nanoLOCK™ Surface Technology Navigated Instruments, and CD Horizon™ Solera™ Voyager™ Spinal System Navigated, Guided, and Powered Drivers

Feb 9, 2022
49 days to decision

K214011 · Product code: **OLO** · Orthopedic
Source: <https://www.510kdatabase.net/k214011/>

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Orthopedic Stereotaxic Instrument (OLO)
Date received	Dec 22, 2021
Decision date	Feb 9, 2022
Days to decision	49 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	Alex Underberg
510(k) history	170 submissions · 159 cleared · 2000-2026

510k Database - www.510kdatabase.net

Device record: <https://www.510kdatabase.net/k214011/>; Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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