FDA 510(k) Premarket Notification

CLEARED

K233951 CD Horizon ModuLeX Spinal System (Shanks, Head Assemblies, and Set Screw)

Mar 27, 2024
103 days to decision

K233951 · Product code: **NKB** · Orthopedic
Source: https://www.510kdatabase.net/k233951/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Thoracolumbosacral Pedicle Screw System (NKB)
Date received	Dec 15, 2023
Decision date	Mar 27, 2024
Days to decision	103 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	Justin O'Connor
510(k) history	170 submissions · 159 cleared · 2000-2026