

K232141 CD Horizon ModuLeX FNS Screw Set (Fenestrated Screw)Aug 16, 2023
29 days to decisionK232141 · Product code: **NKB** · Orthopedic
Source: <https://www.510kdatabase.net/k232141/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Thoracolumbosacral Pedicle Screw System (NKB)
Date received	Jul 18, 2023
Decision date	Aug 16, 2023
Days to decision	29 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary
Other names	CD Horizon ModuLeX Spinal System (Modular Extended Tab Head)

APPLICANT

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

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