

K260216 CD Horizon™ ModuLeX™ Fenestrated Screw SetApr 21, 2026
88 days to decisionK260216 · Product code: **NKB** · Orthopedic
Source: <https://www.510kdatabase.net/k260216/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Thoracolumbosacral Pedicle Screw System (NKB)
Date received	Jan 23, 2026
Decision date	Apr 21, 2026
Days to decision	88 days
Third-party review	No
Combination product	No
PCCP authorized	Yes - Predetermined Change Control Plan (AI/SaMD)
Summary / Statement	Summary
Other names	CD Horizon™ ModuLeX™ Spinal System

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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