

K221646 CD HORIZON™ ASTUTE™ SPINAL SYSTEMOct 4, 2022
120 days to decisionK221646 · Product code: **NKB** · Orthopedic
Source: <https://www.510kdatabase.net/k221646/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Thoracolumbosacral Pedicle Screw System (NKB)
Date received	Jun 6, 2022
Decision date	Oct 4, 2022
Days to decision	120 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary
Other names	CD HORIZON™ Growth Rod Conversion Set; CD HORIZON™ SPINAL SYSTEM; CD Horizon™ Fenestrated Screw Set; COLORADO 2™ SPINAL System; GDLH™ POSTERIOR SPINAL SYSTEM; SHILLA™ Growth Guidance System; TENOR™ SPINAL SYSTEM

APPLICANT

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

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