

K191066 CD Horizon™ Astute™ Spinal SystemOct 3, 2019
164 days to decisionK191066 · Product code: **NQP** · Orthopedic
Source: <https://www.510kdatabase.net/k191066/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Posterior Metal/polymer Spinal System, Fusion (NQP)
Date received	Apr 22, 2019
Decision date	Oct 3, 2019
Days to decision	164 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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

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