

K152338 VERTEX(r) Reconstruction SystemOct 28, 2015
70 days to decisionK152338 · Product code: **NKG** · Orthopedic
Source: <https://www.510kdatabase.net/k152338/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Posterior Cervical Screw System (NKG)
Date received	Aug 19, 2015
Decision date	Oct 28, 2015
Days to decision	70 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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

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