

K254165 Infinity™ OCT SystemJan 21, 2026
30 days to decisionK254165 · Product code: **NKG** · Orthopedic
Source: <https://www.510kdatabase.net/k254165/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Posterior Cervical Screw System (NKG)
Date received	Dec 22, 2025
Decision date	Jan 21, 2026
Days to decision	30 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

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

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