

K253129 Infinity™ OCT SystemOct 24, 2025
29 days to decisionK253129 · Product code: **NKG** · Orthopedic
Source: <https://www.510kdatabase.net/k253129/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Posterior Cervical Screw System (NKG)
Date received	Sep 25, 2025
Decision date	Oct 24, 2025
Days to decision	29 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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k253129/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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