FDA 510(k) Premarket Notification

K253129 Infinity™ OCT System

CLEARED

Oct 24, 2025
29 days to decision

K253129 · 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