FDA 510(k) Premarket Notification

K203678 CD HORIZON™ Spinal System

CLEARED

Jan 15, 2021
29 days to decision

K203678 · Product code: **NQP** · Orthopedic
Source: https://www.510kdatabase.net/k203678/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Posterior Metal/polymer Spinal System, Fusion (NQP)
Date received	Dec 17, 2020
Decision date	Jan 15, 2021
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	Madhuvanthi Soundirarajan
510(k) history	170 submissions · 159 cleared · 2000-2026