

K212428 Centerpiece Plate Fixation SystemDec 13, 2021
131 days to decisionK212428 · Product code: **NQW** · Orthopedic
Source: <https://www.510kdatabase.net/k212428/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Orthosis, Spine, Plate, Laminoplasty, Metal (NQW)
Date received	Aug 4, 2021
Decision date	Dec 13, 2021
Days to decision	131 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Medtronic Sofamor Danek
Location	Memphis, TN, US
Contact	Diamond Wallace
510(k) history	154 submissions · 147 cleared · 2002-2021

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k212428/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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