

K190165 Capstone Control™ Spinal SystemMay 6, 2019
95 days to decisionK190165 · Product code: **MAX** · Orthopedic
Source: <https://www.510kdatabase.net/k190165/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Intervertebral Fusion Device With Bone Graft, Lumbar (MAX)
Date received	Jan 31, 2019
Decision date	May 6, 2019
Days to decision	95 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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

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