FDA 510(k) Premarket Notification

**CLEARED**

# K172199 ELEVATE Spinal System, CAPSTONE PTC Spinal System, CRESCENT Spinal System, CRESCENT Spinal System Titanium

Sep 19, 2017
60 days to decision

K172199 · Product code: **MAX** · Orthopedic
Source: https://www.510kdatabase.net/k172199/

## SUBMISSION DETAILS

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|---|---|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Intervertebral Fusion Device With Bone Graft, Lumbar (MAX) |
| Date received | Jul 21, 2017 |
| Decision date | Sep 19, 2017 |
| Days to decision | 60 days |
| Third-party review | No |
| Summary / Statement | Summary |

## APPLICANT

| | |
|---|---|
| Company | **Medtronic Sofamor Danek** |
| Location | Memphis, TN, US |
| Contact | Justin O'Connor |
| 510(k) history | 154 submissions · 147 cleared · 2002-2021 |