

K211258 Endoskeleton TC Interbody System, Endoskeleton TCS Interbody System, Endoskeleton TA Interbody System, Endoskeleton TAS & TAS Hyp Interbody System, Endoskeleton TL Interbody System, Endoskeleton TL Hyp. Interbody System, Endoskeleton TO Interbody System, Endoskeleton TT Interbody SystemMay 26, 2021
30 days to decisionK211258 · Product code: **MAX** · Orthopedic
Source: <https://www.510kdatabase.net/k211258/>**SUBMISSION DETAILS**

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|-----------------------|--|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Special |
| Device classification | Intervertebral Fusion Device With Bone Graft, Lumbar (MAX) |
| Date received | Apr 26, 2021 |
| Decision date | May 26, 2021 |
| Days to decision | 30 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 | Kelly McDonnell |
| 510(k) history | 170 submissions · 159 cleared · 2000-2026 |

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k211258/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at accessdata.fda.gov. - Generated May 13, 2026