FDA 510(k) Premarket Notification

# K241992 Catalyft™ LS Expandable Interbody System

**CLEARED**

Oct 28, 2024
112 days to decision

K241992 · Product code: **OVD** · Orthopedic
Source: https://www.510kdatabase.net/k241992/

## SUBMISSION DETAILS

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|---|---|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Intervertebral Fusion Device With Integrated Fixation, Lumbar (OVD) |
| Date received | Jul 8, 2024 |
| Decision date | Oct 28, 2024 |
| Days to decision | 112 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 | Rose Merlin Jose |
| 510(k) history | 170 submissions · 159 cleared · 2000-2026 |