FDA 510(k) Premarket Notification

**CLEARED**

# K191148 Medtronic HV-R™ Bone Cement, Kyphon™ Xpede™ Bone Cement, CD Horizon™ Fenestrated Screw Set

Sep 12, 2019
135 days to decision

K191148 · Product code: **PML** · Orthopedic
Source: https://www.510kdatabase.net/k191148/

## SUBMISSION DETAILS

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|---|---|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Bone Cement, Posterior Screw Augmentation (PML) |
| Date received | Apr 30, 2019 |
| Decision date | Sep 12, 2019 |
| Days to decision | 135 days |
| Third-party review | No |
| Summary / Statement | Summary |

## APPLICANT

| | |
|---|---|
| Company | **Medtronic Sofamor Danek USA, Inc.** |
| Location | Memphis, TN, US |
| Contact | Shweta Sharma |
| 510(k) history | 170 submissions · 159 cleared · 2000-2026 |