FDA 510(k) Premarket Notification

**CLEARED**

# K171938 KYPHON Xpede Bone Cement, CD HORIZON Fenestrated Screw Set

Oct 23, 2017
117 days to decision

K171938 · Product code: **PML** · Orthopedic
Source: https://www.510kdatabase.net/k171938/

## SUBMISSION DETAILS

| | |
|---|---|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Bone Cement, Posterior Screw Augmentation (PML) |
| Date received | Jun 28, 2017 |
| Decision date | Oct 23, 2017 |
| Days to decision | 117 days |
| Third-party review | No |
| Summary / Statement | Summary |

## APPLICANT

| | |
|---|---|
| Company | **Medtronic** |
| Location | Minneapolis, MN, US |
| Contact | Lee Grant |
| Website | http://www.medtronic.com/us-en/index.html |
| 510(k) history | 32 submissions · 32 cleared · 2007-2026 |

Medtronic is an American-Irish medical device company with operational headquarters in Minneapolis, Minnesota. The company operates globally across more than 150 countries and is the largest medical device company in the world by revenue. Medtronic has received FDA 510(k) clearances from total submissions since 2007. The company's regulatory portfolio is dominated by cardiovascular devices, including oxygenation systems, arterial filters, cardioplegia delivery systems, and catheter-based interventions. Medtronic also maintains a significant presence in orthopedic spinal s...