

**K191148 Medtronic HV-R™ Bone Cement, Kyphon™ Xpede™ Bone Cement, CD Horizon™ Fenestrated Screw Set**Sep 12, 2019  
135 days to decisionK191148 · 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**

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

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k191148/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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