

**K151227 KYPHON XPEDE Bone Cement**Nov 16, 2015  
193 days to decisionK151227 · Product code: **NDN** · Orthopedic  
Source: <https://www.510kdatabase.net/k151227/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Cement, Bone, Vertebroplasty (NDN)
Date received	May 7, 2015
Decision date	Nov 16, 2015
Days to decision	193 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Medtronic</b>
Location	Minneapolis, MN, US
Contact	KATHY L REMSEN
Website	<a href="http://www.medtronic.com/us-en/index.html">http://www.medtronic.com/us-en/index.html</a>
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...

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