

**K152604 KYPHON HV-R Fenestrated Screw Cement, CD
HORIZON Fenestrated Screw Set**Jan 6, 2016
117 days to decisionK152604 · Product code: **PML** · Orthopedic
Source: <https://www.510kdatabase.net/k152604/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Bone Cement, Posterior Screw Augmentation (PML)
Date received	Sep 11, 2015
Decision date	Jan 6, 2016
Days to decision	117 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Medtronic Sofamor Danek USA, Incorporated
Location	Memphis, TN, US
Contact	Pamela Edwards
510(k) history	2 submissions · 2 cleared · 2015-2016

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