

K180700 KYPHON HV-R Bone CementMay 18, 2018
63 days to decisionK180700 · Product code: **NDN** · Orthopedic
Source: <https://www.510kdatabase.net/k180700/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Cement, Bone, Vertebroplasty (NDN)
Date received	Mar 16, 2018
Decision date	May 18, 2018
Days to decision	63 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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

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