

**K251193 Grafton™ DBM**Jun 12, 2025  
56 days to decisionK251193 · Product code: **MQV** · Orthopedic  
Source: <https://www.510kdatabase.net/k251193/>**SUBMISSION DETAILS**

---

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Filler, Bone Void, Calcium Compound (MQV)
Date received	Apr 17, 2025
Decision date	Jun 12, 2025
Days to decision	56 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary
Other names	Grafton Plus™ DBM Paste; Magnifuse™ Bone Graft

**APPLICANT**

---

Company	<b>Medtronic Sofamor Danek, Inc.</b>
Location	Memphis, TN, US
Contact	Ian Dunkley
510(k) history	99 submissions · 89 cleared · 2000-2025

**REGULATORY CONSULTANT**

---

Consulting firm	<b>Bruder Consulting &amp; Venture Group</b>
Contact	Scott Bruder

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: FDA [accessdata.fda.gov](https://accessdata.fda.gov)

---

**510k Database** - [www.510kdatabase.net](https://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k251193/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](https://accessdata.fda.gov)).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at [accessdata.fda.gov](https://accessdata.fda.gov). - Generated May 13, 2026