FDA 510(k) Premarket Notification

K251193 Grafton™ DBM

CLEARED

Jun 12, 2025
56 days to decision

K251193 · 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	**Medtronic Sofamor Danek, Inc.**
Location	Memphis, TN, US
Contact	Ian Dunkley
510(k) history	99 submissions · 89 cleared · 2000-2025

REGULATORY CONSULTANT

Consulting firm	**Bruder Consulting & Venture Group**
Contact	Scott Bruder

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