June 12, 2025

Medtronic Sofamor Danek, Inc.
% Scott Bruder
Founder and CEO
Bruder Consulting & Venture Group
38 True Harbour Way
West Islip, New York 11795

Re: K251193
Trade/Device Name: Grafton™ DBM; Grafton Plus™ DBM Paste; Magnifuse™ Bone Graft
Regulation Number: 21 CFR 888.3045
Regulation Name: Resorbable calcium salt bone void filler device
Regulatory Class: Class II
Product Code: MQV, MBP
Dated: April 17, 2025
Received: April 17, 2025

Dear Scott Bruder:

We have reviewed your section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (the Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database available at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR Part 803) for devices or postmarketing safety reporting (21 CFR Part 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-

assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

JESSE MUIR -S Digitally signed by JESSE MUIR -S
Date: 2025.06.12 12:05:45 -04'00'

Jesse Muir, Ph.D.
Assistant Director
DHT6C: Division of Restorative, Repair and Trauma Devices
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Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 07/31/2026
See PRA Statement below.

Submission Number *(if known)*

K251193

Device Name

Grafton™ DBM;
Grafton Plus™ DBM Paste;
Magnifuse™ Bone Graft

Indications for Use *(Describe)*

Grafton™ DBM and Grafton Plus ™ DBM Paste are intended for use as a bone graft extender, bone graft substitute, and bone void filler in bony voids or gaps of the skeletal system (i.e., posterolateral spine, intervertebral disc space (excluding Flex or Crunch), pelvis and extremities) not intrinsic to the stability of the bony structure. The voids or gaps may be surgically created defects or defects created by traumatic injury to the bone. When used in intervertebral body fusion procedures, Graft™ DBM (excluding Flex or Crunch) and Grafton Plus ™ DBM Paste must be used with an intervertebral body fusion device cleared by FDA for use with a bone void filler.
Grafton™ DBM and Grafton Plus™ DBM Paste are absorbed/remodeled and replaced by host bone during the healing process.

Magnifuse™ Bone Graft is intended for use as a bone graft substitute in bony voids or gaps of the skeletal system (i.e., posterolateral spine, intervertebral disc space, pelvis and extremities) not intrinsic to the stability of the bony structure. Voids or gaps may be surgically created defects or defects created by traumatic injury to the bone.
Magnifuse™ Bone Graft may be used in a manner comparable to autogenous bone or allograft bone. Magnifuse™ Bone Graft may be mixed with fluid such as bone marrow aspirate, blood, sterile water, or sterile water in order to adjust consistency and handling of bone graft material.
When used in intervertebral body fusion procedures, Magnifuse™ Bone Graft must be used with an intervertebral body fusion device cleared by FDA for use with a bone void filler.
Magnifuse™ Bone Graft is resorbed/remodeled and is replaced by host bone during the healing process.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

510(k) Summary

Submitter
Medtronic Sofamor Danek, Inc.
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Date Prepared
June 6, 2025

Device

Trade Name	Grafton™ DBM Grafton Plus™ DBM Paste Magnifuse™ Bone Graft
Common Name	Bone void filler
Regulation	21 CFR 888.3045 Resorbable calcium salt bone void filler device
Classification	Class II
Product Code	MQV, MBP
Panel	Orthopedic

Predicates

Primary Predicate	NuVasive - Attrax Putty (K203714)
Secondary Predicate	Prosidyan - Fibergraft™ BG Putty (K222276)
Reference Devices	GRAFTON® DBM (K051195) GRAFTON PLUS® DBM Paste (K043048) GRAFTON® II eDBM (K082615)

Device Description
The Grafton™ DBM, Grafton Plus™ DBM Paste, and Magnifuse™ Bone Graft devices in this submission are human bone products containing human demineralized bone matrix (DBM).

> **Grafton™ DBM** is a human bone product that contains human DBM with an inert additive. Grafton™ DBM is produced in particular physical forms (Grafton™ DBM Gel, Grafton™ DBM Putty, Grafton™ DBM Matrix, Grafton™ DBM Orthoblend) and/or handling property. Grafton™ DBM is provided in ready-to-use form and is intended in

single patient, single use containers. Grafton™ DBM is identical to the device cleared in K051195.

Grafton Plus ™ DBM Paste is human demineralized bone matrix (DBM) combined with an inert additive to yield a product having a particular physical form and/or handling property. Grafton Plus™ DBM Paste is identical to the device cleared in K043048.

Magnifuse™ Bone Graft is a human bone allograft product containing human DBM and surface demineralized cortical bone chips sealed in an absorbable mesh pouch for intraoperative handling. It is intended for use in filling bony voids or gaps or the skeletal system not intrinsic to the stability of the bony structure. Magnifuse™ Bone Graft is provided ready-to-use in various package sizes by volume or dimension and is intended for single patient use. Magnifuse™ Bone Graft is identical to the device cleared in K082615.

Indications for Use Statement

Grafton™ DBM and Grafton Plus ™ DBM Paste are intended for use as a bone graft extender, bone graft substitute, and bone void filler in bony voids or gaps of the skeletal system (i.e., posterolateral spine, intervertebral disc space (excluding Flex and Crunch), pelvis, and extremities) not intrinsic to the stability of the bony structure. The voids or gaps may be surgically created defects or defects created by traumatic injury to the bone.

When used in intervertebral body fusion procedures, Grafton™ DBM (excluding Flex and Crunch) and Grafton Plus™ DBM Paste must be used with an intervertebral body fusion device cleared by FDA for use with a bone void filler.

Grafton™ DBM and Grafton Plus™ DBM Paste are absorbed/remodeled and replaced by host bone during the healing process.

Magnifuse™ Bone Graft is intended for use as a bone graft substitute in bony voids or gaps of the skeletal system (i.e., posterolateral spine, intervertebral disc space, pelvis, and extremities) not intrinsic to the stability of the bony structure. Voids or gaps may be surgically created defects or defects created by traumatic injury to the bone.

Magnifuse™ Bone Graft may be used in a manner comparable to autogenous bone or allograft bone. Magnifuse™ Bone Graft may be mixed with fluid such as bone marrow aspirate, blood, sterile water, or sterile saline in order to adjust consistency and handling of bone graft material.

When used in intervertebral body fusion procedures, Magnifuse™ Bone Graft must be used with an intervertebral body fusion device cleared by FDA for use with a bone void filler.

Magnifuse™ Bone Graft is resorbed/remodeled and is replaced by host bone during the healing process.

Substantial Equivalence
This submission expands the devices' indications for use to include use in the intervertebral disc space. The intended use is the same for subject and predicate devices, which are cleared for use in intervertebral disc space. There are differences in the devices' material composition, but this does not raise different questions of safety and effectiveness. The effect of differences in material composition is addressed in the prior functional animal model performance.

Performance
The subject devices have been previously cleared under K051195, K043048, K082615, which serve as Reference Devices. These submissions are leveraged to support the devices' DBM, viral inactivation, shelf-life, endotoxin, pyrogenicity, biocompatibility, and characterizations/bench performance. The devices' performance in the intervertebral body space was supported by a robust analysis of bone grafting materials in the prior posterolateral spine fusion studies.

Summary
The subject devices and predicates have the same intended use, and the same specific indications for use in the intervertebral disc space of the spine. Any differences in technological characteristics between the subject devices and predicate do not raise different questions of safety and effectiveness. Based on the clinical analysis, Medtronic concludes that the devices are substantially equivalent to the predicates.