January 17, 2025

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

Re: K243706
Trade/Device Name: Mastergraft™ Matrix EXT; Mastergraft™ Strip; Mastergraft™ Putty; Mastergraft™ Granules
Regulation Number: 21 CFR 888.3045
Regulation Name: Resorbable Calcium Salt Bone Void Filler Device
Regulatory Class: Class II
Product Code: MQV
Dated: November 26, 2024
Received: November 29, 2024

Dear Dr. 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,

Robert M. Stefani -S

Digitally signed by Robert M. Stefani -S
Date: 2025.01.17 11:32:41 -05'00'

For: Jesse Muir, Ph.D.
Assistant Director
DHT6C: Division of Restorative, Repair, and Trauma Devices
OHT6: Office of Orthopedic Devices
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)*

K243706

Device Name

Mastergraft™ Matrix EXT;
Mastergraft™ Strip;
Mastergraft™ Putty;
Mastergraft™ Granules

Indications for Use *(Describe)*

Mastergraft™ Matrix EXT is to be combined with autogenous bone marrow and is indicated for bony voids or gaps not intrinsic to the stability of the bony structure and can be used as a bone graft extender. The device is to be gently packed into bony voids or gaps of the skeletal system (i.e., the posterolateral spine, intervertebral disc space, pelvis, ilium, and/or extremities). These defects may be surgically created osseous defects or osseous defects created from traumatic injury to the bone. The device resorbs and is replaced with bone during the healing process. When used in intervertebral body fusion procedures, Mastergraft™ Matrix EXT must be used with an intervertebral body fusion device cleared by FDA for use with a bone void filler.

Mastergraft™ Strip is to be combined with autogenous bone marrow and is indicated for bony voids or gaps that are not intrinsic to the stability of the bony structure and can be used as a bone graft extender.
The device is to be gently packed into bony voids or gaps of the skeletal system (i.e., the posterolateral spine, intervertebral disc space, pelvis, ilium, and/or extremities). These defects may be surgically created osseous defects or osseous defects created from traumatic injury to the bone. The device resorbs and is replaced with bone during the healing process. When used in intervertebral body fusion procedures, Mastergraft™ Strip must be used with an intervertebral body fusion device cleared by FDA for use with a bone void filler.

Mastergraft™ Putty combined with either autogenous bone marrow, and/or sterile water, and/or autograft is indicated as a bone void filler for bony voids or gaps not intrinsic to the stability of the bony structure. Additionally, Mastergraft™ Putty can be used with autograft as a bone graft extender.
Mastergraft™ Putty is to be gently packed into bony voids or gaps of the skeletal system (e.g., the posterolateral spine, intervertebral disc space, pelvis, ileum, and/or extremities). These defects may be surgically created osseous defects or osseous defects created from traumatic injury to the bone. Mastergraft™ Putty resorbs and is replaced with bone during the healing process. When used in intervertebral body fusion procedures, Mastergraft™ Putty must be used with an intervertebral body fusion device cleared by FDA for use with a bone void filler.

Mastergraft™ Granules is indicated only for bony voids or gaps that are not intrinsic to the stability of the bony structure. Additionally, Mastergraft™ Granules can be used with autograft as a bone graft extender. Mastergraft™ Granules is to be gently packed into bony voids or gaps of the skeletal system (e.g., the posterolateral spine, intervertebral disc space, pelvis, ilium and/or extremities). These defects may be surgically created osseous defects or osseous defects created from traumatic injury to the bone. Mastergraft™ Granules provides a bone void filler that resorbs and is replaced with bone during the healing process. When used in intervertebral body fusion procedures, Mastergraft™ Granules must be used with an intervertebral body fusion device cleared by FDA for

use with a bone void filler.

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.

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510(k) Summary

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Date Prepared
November 27, 2024

Device

Trade Name	Mastergraft™ Matrix EXT Mastergraft™ Strip Mastergraft™ Putty Mastergraft™ Granules
Common Name	Bone void filler
Regulation	21 CFR 888.3045 Resorbable calcium salt bone void filler device
Classification	Class II
Product Code	MQV
Panel	Orthopedic

Predicates

Primary Predicate	NuVasive - Attrax Putty (K203714)
Secondary Predicate	Prosidyan - Fibergraft™ BG Putty (K222276)
Reference Devices	MASTERGRAFT® Matrix EXT (K141824) MASTERGRAFT® Strip (K082166) MASTERGRAFT® Putty (K071813) MASTERGRAFT® Resorbable Ceramic Granules (K082918)

Device Description
The Mastergraft™ Family of bone grafts in this submission includes Mastergraft™ Matrix EXT, Mastergraft™ Strip, Mastergraft™ Putty, and Mastergraft™ Granules. The devices all include osteoconductive biphasic calcium phosphate ceramic granules in different biocompatible physical forms supplied sterile for single patient use.

Mastergraft™ Matrix EXT is made from a combination of medical grade purified collagen of bovine origin and biphasic calcium phosphate ceramic. In the devices, the collagen is a highly purified (>95%) Type I bioresorbable lyophilized collagen. The biphasic ceramic portion of the device is provided in a 15 percent hydroxyapatite and 85 percent β-tricalcium phosphate formulation. Mastergraft™ Matrix EXT is supplied sterile in a premixed strip form for single patient use. Mastergraft™ Matrix EXT is a biocompatible, osteoconductive, porous implant that allows for bony ingrowth across the graft site while resorbing at a rate consistent with bone healing. The device readily absorbs bone marrow aspirate. Mastergraft™ Matrix EXT is identical to the device cleared in K141824.

Mastergraft™ Strip is made from a combination of medical grade purified collagen of bovine origin and biphasic calcium phosphate ceramic. In the Mastergraft™ Strip device, the collagen is a highly purified (>95%) Type I bioresorbable lyophilized collagen. The biphasic ceramic portion of the device is provided in a 15 percent hydroxyapatite and 85 percent β-tricalcium phosphate formulation. Mastergraft™ Strip is supplied sterile in a premixed strip form for single patient use. Mastergraft™ Strip is a biocompatible, osteoconductive, porous implant that allows for bony ingrowth across the graft site while resorbing at a rate consistent with bone healing. The device readily absorbs bone marrow aspirate and has been shown to heal bone defects. Mastergraft™ Strip is identical to the device cleared in K082166.

Mastergraft™ Putty is made from a combination of medical grade purified collagen of bovine origin and biphasic calcium phosphate ceramic. The collagen component in the Mastergraft™ Putty device is Type I bovine collagen. The biphasic ceramic portion of Mastergraft™ Putty is provided in a 15 percent hydroxyapatite and 85 percent β-tricalcium phosphate formulation. Mastergraft™ Putty is supplied as a sterile, dry, solid, construct hydrated for single patient use and is a moldable form of bone void filler. Mastergraft™ Putty is an osteoconductive, porous implant that allows for bony ingrowth across the graft site while resorbing at a rate consistent with bone healing. Mastergraft™ Putty is biocompatible. Mastergraft™ Putty readily absorbs bone marrow aspirate and was shown to heal bone defects. Mastergraft™ Putty is identical to the device cleared in K071813.

Mastergraft™ Granules is made of medical grade combination of hydroxyapatite and β-tricalcium phosphate. MASTERGRAFT® Granules is provided in a 15 percent hydroxyapatite and 85 percent β-tricalcium phosphate formulation. The product is supplied sterile for single patient use. MASTERGRAFT® Granules is an osteoconductive porous implant. Mastergraft™ Granules is identical to the device cleared in K082918.

Indications for Use Statement

> **Mastergraft™ Matrix EXT** is to be combined with autogenous bone marrow and is indicated for bony voids or gaps not intrinsic to the stability of the bony structure and can be used as a bone graft extender. The device is to be gently packed into bony voids or gaps of the skeletal system (i.e., the posterolateral spine, intervertebral disc space, pelvis, ilium, and/or extremities). These defects may be surgically created osseous defects or osseous defects created from traumatic injury to the bone. The device resorbs and is replaced with bone during the healing process. When used in

intervertebral body fusion procedures, Mastergraft™ Matrix EXT must be used with an intervertebral body fusion device cleared by FDA for use with a bone void filler.

Mastergraft™ Strip is to be combined with autogenous bone marrow and is indicated for bony voids or gaps that are not intrinsic to the stability of the bony structure and can be used as a bone graft extender.
The device is to be gently packed into bony voids or gaps of the skeletal system (i.e., the posterolateral spine, intervertebral disc space, pelvis, ilium, and/or extremities). These defects may be surgically created osseous defects or osseous defects created from traumatic injury to the bone. The device resorbs and is replaced with bone during the healing process. When used in intervertebral body fusion procedures, Mastergraft™ Strip must be used with an intervertebral body fusion device cleared by FDA for use with a bone void filler.

Mastergraft™ Putty combined with either autogenous bone marrow, and/or sterile water, and/or autograft is indicated as a bone void filler for bony voids or gaps not intrinsic to the stability of the bony structure. Additionally, Mastergraft™ Putty can be used with autograft as a bone graft extender.
Mastergraft™ Putty is to be gently packed into bony voids or gaps of the skeletal system (e.g., the posterolateral spine, intervertebral disc space, pelvis, ileum, and/or extremities). These defects may be surgically created osseous defects or osseous defects created from traumatic injury to the bone. Mastergraft™ Putty resorbs and is replaced with bone during the healing process. When used in intervertebral body fusion procedures, Mastergraft™ Putty must be used with an intervertebral body fusion device cleared by FDA for use with a bone void filler.

Mastergraft™ Granules is indicated only for bony voids or gaps that are not intrinsic to the stability of the bony structure. Additionally, Mastergraft™ Granules can be used with autograft as a bone graft extender. Mastergraft™ Granules is to be gently packed into bony voids or gaps of the skeletal system (e.g., the posterolateral spine, intervertebral disc space, pelvis, ilium and/or extremities). These defects may be surgically created osseous defects or osseous defects created from traumatic injury to the bone. Mastergraft™ Granules provides a bone void filler that resorbs and is replaced with bone during the healing process. When used in intervertebral body fusion procedures, Mastergraft™ Granules must be used with an intervertebral body fusion device cleared by FDA for use with a bone void filler.

Substantial Equivalence
This submission expands the device's 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 device's 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 K141824, K082166, K071813, and K082918, which serve as Reference Devices. These submissions are leveraged to support the device's sterility, shelf-life, endotoxin, pyrogenicity, biocompatibility, and characterizations/bench performance as recommended in FDA's *Class II Special Controls Guidance Document for Resorbable Calcium Salt Bone Void Filler Devices*. The device's performance in intervertebral spine was supported by a robust analysis of bone grafting materials in the prior posterolateral spine fusion studies.

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