DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

Medtronic Sofamor Danek USA, Incorporated
Mr. Gregory Maschek
Senior Regulatory Affairs Manager
1800 Pyramid Place
Memphis, Tennessee 38132

August 14, 2015

Re: K151172
Trade/Device Name: Mastergraft® Contain
Regulation Number: 21 CFR 888.3045
Regulation Name: Resorbable calcium salt bone void filler device
Regulatory Class: Class II
Product Code: MQV
Dated: July 8, 2015
Received: July 9, 2015

Dear Mr. Mascheck:

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 (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. 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.

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 803); good manufacturing practice requirements as set forth in the

quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mark N. Melkerson -S

Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K151172

Device Name
MASTERGRAFT® Contain

Indications for Use *(Describe)*
MASTERGRAFT® Contain 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, 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 the pelvis, ilium, or extremities, the device is to be used with bone marrow aspirate. When used in the posterolateral spine, the device must be mixed with bone marrow aspirate and autograft bone and used as a bone graft extender.

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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

510(K) Summary

I. SUBMITTER NAME & ADDRESSS: Medtronic Sofamor Danek USA, Inc
1800 Pyramid Place
Memphis, Tennessee 38132
Telephone: (901) 396-3133
Fax: (901) 346-9738
Establishment Registration: 1030489

CONTACT PERSON: Gregory Maschek
Sr. Regulatory Affairs Specialist

DATE PREPARED: July 7, 2015

II. PROPOSED PROPRIETARY TRADE NAME: MASTERGRAFT® Contain

DEVICE CLASSIFICATION NAME: Resorbable Calcium Salt Bone Void Filler
REGULATION NUMBER: 21 CFR 888.3045
CLASSIFICATION PRODUCT CODE: MQV
CLASS: II

III. IDENTIFICATION OF LEGALLY MARKETED DEVICES:

Table 1. Legally Marketed Devices

Device name	510(k) number	Substantial Equivalence date
MASTERGRAFT® Strip	K082166	06/02/2009
MASTERGRAFT® MATRIX EXT	K130335	04/19/2013

IV. DEVICE DESCRIPTION:

MASTERGRAFT® Contain is made from a combination of medical grade purified collagen of bovine origin and biphasic calcium phosphate ceramic. In the MASTERGRAFT® Contain 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 ß- tricalcium phosphate formulation. The device is supplied sterile in a premixed form for single patient use. The device 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. The device is designed with a cavity (ies) to contain and deliver autologous bone to the surgical site when used as a bone graft extender.

The purpose of this Traditional 510(k) application is to add MASTERGRAFT® Contain to the MASTERGRAFT® product family. The material composition of MASTERGRAFT® Contain is identical to that of predicate devices MASTERGRAFT® Strip and MASTERGRAFT® Matrix EXT. The intended use (i.e., bone void filler and posterolateral spine bone graft extender) of MASTERGRAFT® Contain are similar to that of predicate devices MASTERGRAFT® Strip and MASTERGRAFT® Matrix EXT. The overall dimensions of the MASTERGRAFT® Contain devices are similar to MASTERGRAFT® Strip and MASTERGRAFT® Matrix EXT, with the addition of a cavity to contain and deliver autogenous bone to the implant site when used as bone graft extender. Compared to the predicate devices, the inclusion of the cavity in the design of MASTERGRAFT® Contain does not present a new worst case for safety or effectiveness of the device for its intended use.

V. INDICATIONS FOR USE:

MASTERGRAFT® Contain 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, 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 the pelvis, ilium, or extremities, the device is to be used with bone marrow aspirate. When used in the posterolateral spine, the device must be mixed with bone marrow aspirate and autograft bone and used as a bone graft extender.

VI. SUMMARY OF THE TECHNOLOGICAL CHARACTERISTICS:

Table 2. Summary of the technological Characteristics

Comparison Feature	**Subject** **MASTERGRAFT ® Contain**	**Predicate** **MASTERGRAFT® Strip K082166** **S.E. 06/02/2009**	**Predicate** **MASTERGRAFT® Matrix EXT K130335 S.E. 04/19/2013**
Indication for Use	Similar	S.E. 06/02/2009	S.E. 04/19/2013
Fundamental Scientific Technology • Operating Principle • Mechanism of Action	Identical	S.E. 06/02/2009	S.E. 04/19/2013
Sizes	Similar	S.E. 06/02/2009	S.E. 04/19/2013
Performance	Identical	S.E. 06/02/2009	S.E. 04/19/2013
Sterilization	Identical	S.E. 06/02/2009	S.E. 04/19/2013
Manufacturing principles	Identical	S.E. 06/02/2009	S.E. 04/19/2013
Shelf-Life	Identical	S.E. 06/02/2009	S.E. 04/19/2013
Packaging	Identical	S.E. 06/02/2009	S.E. 04/19/2013
Material Composition • Collagen • Granules	Identical	S.E. 06/02/2009	S.E. 04/19/2013
Use of rigid fixation	Identical	S.E. 06/02/2009	S.E. 04/19/2013
Safety and Effectiveness profile	Identical	S.E. 06/02/2009	S.E. 04/19/2013
Geometry	Similar	S.E. 06/02/2009	S.E. 04/19/2013

VII. DISCUSSION OF NON-CLINICAL TESTING:

Non-clinical testing was performed in support of substantial equivalence for the cited predicate K082166 [S.E. 06/02/2009] in accordance with FDA Recognized Consensus Standards and FDA Guidelines, where applicable. No new non-clinical testing was performed or submitted in support of this 510(k).

Previously submitted non-clinical testing was performed in accordance with the following standards:

- ASTM F1185-03: 2009 Specification for Composition of Ceramic Hydroxyapatite for Surgical Implants
- ASTM F1088-04a: 2010, Specification for β-tricalcium Phosphate for Surgical Implantation
- ISO 22442-1: 2007 Animal Tissues and Their Derivatives Utilized in the Manufacture of Medical Devices -- Part 1 Analysis and Risk Management
- ISO 22442-2: 2007 Animal Tissues and Their Derivatives Utilized in the Manufacture of Medical Devices -- Part 2 Controls on Sourcing, Collection, and Handling
- ISO 22442-3: 2007 Animal Tissues and Their Derivatives Utilized in the Manufacture of Medical Devices -- Part 3 Validation of the Elimination and/or Inactivation of Virus and Transmissible Agents
- ISO 10993-3: 2003/(R) 2009, Biological evaluation of medical devices -- Part 3 Tests for genotoxicity, carcinogenicity, and reproductive toxicity. (Biocompatibility)
- ISO10993-4: 2009, Biological evaluation of medical devices -- Part 4: Selection of tests for interactions with blood
- ISO 10993-5: 2009, Biological evaluation of medical devices -- Part 5: Tests for In Vitro cytotoxicity. (Biocompatibility)
- ISO 10993-6: 2009, Biological evaluation of medical devices -- Part 6: Tests for local effects after implantation. (Biocompatibility)

- ISO 10993-10: 2009, Biological evaluation of medical devices -- Part 10: Tests for irritation and skin sensitization. (Biocompatibility)
- ISO 10993-11: 2009, Biological evaluation of medical devices -- Part 11: Tests for systemic toxicity. (Biocompatibility)
- ISO 10993-12: 2009, Biological evaluation of medical devices -- Part 12: Sample preparation and reference materials. (Biocompatibility)

VIII. CONCLUSION:

Documentation provided in this submission demonstrates that the subject device is substantially equivalent to the previously cleared bone void filler MASTERGRAFT® Strip [K082166 S.E. 06/02/2009] and MASTERGRAFT® Matrix EXT [K130335 S.E. 04/19/2013.]

The subject device is substantially equivalent to predicates MASTERGRAFT® Strip and MASTERGRAFT® Matrix EXT in several categories including: indication, material composition (including biphasic calcium phosphate granules and collagen), sterility, shelf-life, biocompatibility and the ability to resorb during the healing process.