K122513
1/3

MAR 0 6 2013

510(K) Summary

I.	**SUBMITTER NAME AND ADDRESS:**	Medtronic Sofamor Danek USA 1800 Pyramid Place Memphis, Tennessee 38132 Telephone: (901) 396-3133 Fax: (901) 346-9738 Establishment Registration: 1030489
	CONTACT PERSON:	Kelly Anglin Sr. Regulatory Affairs Specialist
	DATE PREPARED:	February 14, 2013
II.	**PROPOSED PROPRIETARY TRADE NAME:**	MAGNIFUSE® II BONE GRAFT
	DEVICE CLASSIFICATION NAME:	Filler, bone void, calcium compound
	REGULATION NUMBER:	21 CFR 888.3045
	REGULATION NAME:	Resorbable calcium salt bone void filler device
	REGULATORY CLASS:	II
	PRODUCT CODE:	MQV, MBP

III. **IDENTIFICATION OF LEGALLY MARKETED DEVICES:**
Grafton® II eDBM (K082615, SE 10/16/2008)

IV. **DEVICE DESCRIPTION:**
MAGNIFUSE® II Bone Graft is assembled by the clinician at the time of the procedure using the supplied human bone allograft tissue matrix mixed 1:1 with autograft tissue. The mixture is packed into a polyglycolic acid (PGA) resorbable mesh bag with the supplied injection molded plastic spatula, funnel, and plunger. This product enables clinicians to generate a construct having a particular physical form and handling property. No additional carrier is added to the allograft material.

This MAGNIFUSE® II Bone Graft product was prepared from human bone tissue recovered from a cadaveric donor using aseptic surgical techniques and microbiologically tested during recovery. As a biological material, some variations in the product should be expected in both handling and appearance. The final product in packaged form was tested for sterility according to the procedures in the current U.S. Pharmacopoeia USP standard <71>.

V. **INDICATIONS FOR USE:**

MAGNIFUSE® II Bone Graft is intended for use as a bone graft substitute in bony voids or gaps of the skeletal system (i.e., posterolateral spine and pelvis) 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. MAGNIFUSE® II Bone Graft is resorbed/remodeled and replaced by host bone during the healing process.

VI. SUMMARY OF THE TECHNOLOGICAL CHARACTERISTICS:

Characteristic	Subject Device: MAGNIFUSE® II Bone Graft	Predicate Device GRAFTON® II eDBM
Product Preparation Instruction	Addition of autograft to mesh bag using provided spatula, funnel and syringe	K082615 (SE 10/16/2008)
Operating Principle	Identical	K082615 (SE 10/16/2008)
Basic Design	Identical	K082615 (SE 10/16/2008)
Performance	Identical	K082615 (SE 10/16/2008)

VIII. SUMMARY OF NON-CLINICAL TESTING

A Rabbit posterlateral lumbar fusion study was conducted to evaluate the bone formation capability of MAGNIFUSE® II Bone Graft. The autograft group fusion rates were consistent with the literature and previous laboratory results in this model, suggesting a valid fusion test. The predicate MAGNIFUSE ® Bone Graft manual fusion rate was equal to autograft rate but the radiographic fusion rate was higher with MAGNIFUSE ® Bone Graft. The fusion rates for the subject MAGNIFUSE ® II Bone Graft exhibited comparable fusion rates to the autograft group. All animals tolerated the graft material well and exhibited remodeling of the graft site over the duration of the study.

The allograft tissue supplied as a subcomponent of the subject MAGNIFUSE ® II Bone Graft device is identical in form and processing to the predicate MAGNIFUSE ® device cleared under eDBM K082165 (S.E. 10/16/2008). Methods employed to ensure osteoinductivity and viral inactivation of the allograft component are described in further detail in K082615 and subsequent submissions that were cleared by the agency. The allograft tissue subcomponent will be processed via a proprietary processing method that has been shown to consistently produce demineralized bone matrix that is osteoinductive in an athymic rat assay. As the tissue processing is identical to the predicate MAGNIFUSE® device, process consistency for MAGNIFUSE ® II will be confirmed via ongoing testing of the MAGNIFUSE ® finished product for osteoinductivity in this validated athymic rat assay utilizing a five-point linear scale (0, 1, 2, 3, 4) to score

bone formation at 28 days post implantation*. Bone formation in the athymic rat surrogate assay should not be interpreted as a predictor of clinical performance. A full assessment of osteoinductivity of the MAGNIFUSE ® device can be found in K082615. Viral inactivation of MAGNIFUSE® II allograft fibers includes proprietary processing steps of demineralizing acid soaks followed by alcohol soaks and dehydration, as established for the GRAFTON® DBM products (K051195).

Viral inactivation of the cortical chips is done by alcohol soaks and by dehydration using supercritical CO_2 established for viral inactivation cleared in (K061982). These processing steps have been shown and validated to inactivate viruses including; HIV-1; hepatitis B virus; hepatitis C virus, CMV, and Polio virus. These processes further reduce the risk of disease transmission via the use of this product beyond the protection provided by donor testing and screening procedures.

* Edwards etal; Osteoinduction of Human Demineralized Bone: Characterization in a Rat Model. Clinical Orthopaedics, December 1998, Vol 357.

VII. CONCLUSION:

The design features for the subject MAGNIFUSE® II Bone Graft are substantially equivalent to the predicate. Based on the risk analysis and additional supporting documentation provided in this premarket notification, Medtronic believes the subject device demonstrates substantial equivalence to listed predicate device GRAFTON® II eDBM K082165 (S.E. 10/16/2008).

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

March 6, 2013

Medtronic Sofamor Danek USA, Incorporated
% Ms. Kelly Anglin
Senior Regulatory Affairs Specialist
1800 Pyramid Place
Memphis, Tennessee 38132

Re: K122513
Trade/Device Name: MAGNIFUSE® II 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: February 14, 2013
Received: February 19, 2013

Dear Ms. Anglin:

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 go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 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 Small Manufacturers, International and Consumer Assistance 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,

Erin D Keith

Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known):

Device Name: MAGNIFUSE® II Bone Graft

INDICATIONS FOR USE:
MAGNIFUSE® II Bone Graft is intended for use as a bone graft substitute in bony voids or gaps of the skeletal system (i.e., posterolateral spine and pelvis) 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. MAGNIFUSE® II Bone Graft is resorbed/remodeled and replaced by host bone during the healing process.

Prescription Use __X__ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Laurence D. Coyne -A

(Division Sign-Off)
Division of Orthopedic Devices
510(k) Number: K122513