November 16, 2017

SeaSpine Orthopedics Corporation
Ms. Caryn Sailor
Regulatory Affairs Specialist
5770 Armada Drive
Carlsbad, California 92008

Re: K172130
Trade/Device Name: Resorbable Mesh Device
Regulation Number: 21 CFR 888.3045
Regulation Name: Resorbable calcium salt bone void filler device
Regulatory Class: Class II
Product Code: MQV, MBP
Dated: October 18, 2017
Received: October 19, 2017

Dear Ms. Sailor:

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.

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.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Katherine D. Kavlock -S

for
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)*
K172130

Device Name
Resorbable Mesh Device

Indications for Use *(Describe)*
The Resorbable Mesh Device is intended to fill voids and gaps in the skeletal system that are not intrinsic to the stability of the bony structure. The product is indicated for use with autograft as a bone graft extender in the posterolateral spine and pelvis. The voids or gaps may be surgically created defects or the result of traumatic injury to the bone. The Resorbable Mesh Device is resorbed/remodeled and 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

Contact Details

Owner Operator Name: SeaSpine Orthopedics Corporation
Address: 5770 Armada Drive, Carlsbad CA 92008

Establishment Name: IsoTis OrthoBiologics, Inc.
Address: 2 Goodyear, Irvine, CA 92618

Contact person: Caryn Sailor, Regulatory Affairs Specialist
Email address: caryn.sailor@seaspine.com
Phone number: (949) 855-7174
Fax number: (949) 595-8711

Date Prepared: October 18, 2017

Subject Device

Trade Name: Resorbable Mesh Device
Common Name: Demineralized Bone Matrix Allograft
Classification Name: Resorbable Bone Void Filler
Regulatory Class: II
Regulation: 21 CFR 888.3045
Classification Panel: Orthopedic
Product Code: MQV, MBP

Legally Marketed Predicate Devices

510(k) Number	Product Code	Trade Name	Manufacturer
PRIMARY PREDICATE Device			
K123691	MQV, MBP	MAGNIFUSE Bone Graft	Medtronic Sofamor Danek, Inc.
Additional PREDICATE Devices			
K082615	MQV	GRAFTON II eDBM	OsteoTech, Inc.
K122513	MQV, MBP	MAGNIFUSE II Bone Graft	Medtronic Sofamor Danek, Inc.

Device Description

The Resorbable Mesh Device is comprised of a resorbable mesh pouch containing demineralized human cortical bone in particulate form processed by FDA registered, AATB-accredited tissue banks. The resorbable mesh pouch is knitted from poly(lactic-co-glycolic) acid (PLGA) fibers which have a high glycolide content.

The Resorbable Mesh Device is offered in various sizes and provided in individually sterile packaged units and ready-to-use. The product is terminally sterilized by

electron beam irradiation and validated to ensure a minimum Sterility Assurance Level (SAL) of 10^{-6}.

Indications for Use

The Resorbable Mesh Device is intended to fill voids and gaps in the skeletal system that are not intrinsic to the stability of the bony structure. The product is indicated for use with autograft as a bone graft extender in the posterolateral spine and pelvis. The voids or gaps may be surgically created defects or the result of traumatic injury to the bone. The Resorbable Mesh Device is resorbed/remodeled and replaced by host bone during the healing process.

Summary of Non-Clinical Testing to Support Substantial Equivalence

Non-clinical testing performed on the Resorbable Mesh Device includes tests for: biocompatibility, sterilization, bacterial endotoxin, viral inactivation/clearance, osteoinductive potential and *in vivo* (animal) safety and performance. Biocompatibility was performed in accordance with *ISO 10993-1, Biological Evaluation of Medical Devices – Part 1: Evaluation and testing within a risk management process* and test results were acceptable for a permanent, bone/tissue-contacting implantable device. Sterilization complies with *ISO 11137, Sterilization of Sterilization of Health Care products - Radiation* and has been validated to ensure a sterility assurance level (SAL) of 10^{-6}. Bacterial endotoxin testing complies with *AAMI ST72 Bacterial Endotoxins – Test Methods, Routine Monitoring, and Alternatives to Batch Testing* and *USP<85> Bacterial Endotoxin Test* and has been validated ensure a BET limit of ≤20 EU/Device. A viral inactivation/clearance study evaluated a panel of model viruses representing various virus types, sizes, shapes and genomes. The DBM processing method was determined to provide significant viral inactivation/clearance potential for a wide range of potential viruses.

Each lot of DBM in the Resorbable Mesh Device is tested for osteoinductive potential using the athymic rodent model. Only DBM demonstrating osteoinductive potential is used to manufacture the Resorbable Mesh Device. It is unknown how osteoinductive potential measured in the athymic rodent model correlates with clinical performance.

An *in vivo* study of the Resorbable Mesh Device demonstrated comparable resorption, remodeling and rates of fusion when compared to an autograft control. The study employed various analyses and endpoints were assessed at several time points.

Conclusions

The submitted data demonstrate that the Resorbable Mesh Device is substantially equivalent to the predicate in terms of all relevant characteristics including intended use, indications for use, materials, performance, biocompatibility, osteoinductive potential and viral inactivation/clearance. Specifically, both the Resorbable Mesh Device and the MAGNIFUSE Bone Graft contain demineralized human cortical bone contained in a sealed resorbable polymer mesh pouch, intended as a bone graft

extender in the posterolateral spine or pelvis. Like the MAGNIFUSE Bone Graft, the demineralized bone in the Resorbable Mesh Device has been validated using standard test methods for viral inactivation/clearance and for osteoinductive potential. The mesh pouch of the Resorbable Mesh Device and the MAGNIFUSE Bone Graft are composed of resorbable PLGA and PGA, respectively, which are comparable in terms of material characteristics, resorption profile and function (to contain DBM).