October 4, 2021

SeaSpine Corporation
Caryn Sailor
Associate Manager, Regulatory Affairs
2 Goodyear
Irvine, California 92618

Re: K212135
Trade/Device Name: Dry DBM-A Putty
Regulation Number: 21 CFR 888.3045
Regulation Name: Resorbable Calcium Salt Bone Void Filler Device
Regulatory Class: Class II
Product Code: MQV, MBP
Dated: July 9, 2021
Received: July 12, 2021

Dear Caryn 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. 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 located 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.

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) for devices or postmarketing safety reporting (21 CFR 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 4, Subpart A) for combination products; 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 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,

Laura C. Rose, 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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*

K212135

Device Name
Dry DBM-A Putty

Indications for Use *(Describe)*

Dry DBM-A Putty 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

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 K212135

Contact Details

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

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

Contact person: Caryn Sailor, Associate Manager, Regulatory Affairs
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Phone number: (949) 855-7174
Fax number: (949) 595-8711

Date Prepared: September 24, 2021

Device Name

Device/Trade Name: Dry DBM-A Putty

Common Name: Demineralized Bone Matrix Allograft

Classification: 21 CFR 888.3045

Classification Name: Resorbable Bone Void Filler

Class: II

Product Code: MQV, MBP

Legally Marketed Predicate Device

Predicate – Accell Evo3c

510(k) Number	Product Code	Trade Name	Manufacturer
PRIMARY PREDICATE Device			
K091193	MQV, MBP	Accell Evo3c	IsoTis OrthoBiologics, Inc.*

**IsoTis OrthoBiologics, Inc. is a subsidiary of SeaSpine Orthopedics Corporation. The subject and predicate devices are both manufactured by IsoTis.*

Device Description

Dry DBM-A Putty is made with demineralized human bone mixed with poloxamer resorbable reverse phase medium. Demineralized human bone is in the form of demineralized bone matrix

(DBM) and a dispersed form of DBM, referred to as Accell Bone Matrix (ABM). Cancellous bone chips may also be added. Dry DBM-A Putty is formulated into a freeze-dried putty form and is provided in a sterile, single use package. As a human-derived material, some variations in the product should be expected, such as appearance and handling. Dry DBM-A Putty is packaged in a standard syringe.

The device is hydrated at the point of use with saline, blood, or bone marrow aspirate (BMA) (hydration fluid). Utilizing a standard male luer syringe available to the clinician in the Operating Room (not provided with the finished device), it is recommended to hydrate at a 0.8:1 fluid volume (relative to the stated graft volume). The hydration fluid is dispensed from the male luer syringe into the device syringe until reconstitution of the dry putty is achieved.

Intended Use/Indications for Use

Dry DBM-A Putty 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.

Summary of Technological Characteristics

The subject device is similar to the cited predicate device in regard to components, device description, intended use/indications for use, device characteristics (design, materials, sterility, manufacturing, etc.) and performance.

Summary of Non-Clinical Testing to Support Substantial Equivalence

Non-clinical testing performed on the subject device includes tests for: bacterial endotoxin, *in vivo* (animal) safety and performance, sterilization, viral inactivation/clearance, osteoinductive potential, and product shelf-life. As the subject and predicate devices utilize equivalent raw materials, manufacturing processes, packaging, and sterilization, the subject device does not introduce a new worst case for biocompatibility. 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. An *in vivo* (animal) study for safety and performance 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. Sterilization complies with *ISO 11137, Sterilization of Sterilization of Health Care Products – Radiation* to ensure a sterility assurance level (SAL) of 10^{-6}. The viral clearance study concluded significant viral inactivation/clearance potential for a wide range of potential viruses. Product shelf-life testing was evaluated to ensure that the subject device maintains osteoinductive potential, acceptable hydration, and sterility over the labeled shelf life.

Clinical Testing

Not applicable; determination of substantial equivalence is not based on an assessment of clinical performance data.

Conclusions

The submitted data demonstrate that the subject device is substantially equivalent to the cited legally marketed predicate.