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

May 11, 2020

Re: K200290
Trade/Device Name: Resorbable Mesh Pouch (Ballast® MT, OsteoBallast® MT)
Regulation Number: 21 CFR 888.3045
Regulation Name: Resorbable Calcium Salt Bone Void Filler Device
Regulatory Class: Class II
Product Code: MQV
Dated: April 8, 2020
Received: April 9, 2020

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. 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,

Jesse Muir, Ph.D.
Acting 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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K200290

Device Name
Resorbable Mesh Pouch (Trade names: Ballast MT, OsteoBallast MT)

Indications for Use *(Describe)*
The Resorbable Mesh Pouch, once filled with autograft, 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 in the posterolateral spine and pelvis as a bone void filler and bone graft extender. The voids or gaps may be surgically created defects or the result of traumatic injury to the bone. Ultimately, the Resorbable Mesh Pouch will be resorbed.

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 K200290

Contact Details

Owner Operator Name: SeaSpine Orthopedics Corporation
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Contact person: Caryn Sailor, Manager, Regulatory Affairs
Email address: caryn.sailor@seaspine.com

Date Prepared: May 11, 2020

Device Name

Trade Name: Resorbable Mesh Pouch (Ballast® MT, OsteoBallast® MT)

Common Name: Bone Void Filler

Classification: 21 CFR 888.3045

Classification Name: Resorbable Bone Void Filler

Class: II

Product Code: MQV

Legally Marketed Predicate Device

Predicate – Resorbable Mesh Device

510(k) Number	Product Code	Trade Name	Manufacturer
PRIMARY PREDICATE Device			
K172130	MQV	Resorbable Mesh Device (Ballast, OsteoBallast)	IsoTis OrthoBiologics, Inc.

Device Description

The Resorbable Mesh Pouch is comprised of an empty bioresorbable poly(lactic-co-glycolic) acid (PLGA) pouch (open at one end and sealed at the other) and disposable polypropylene accessories. Utilizing the provided accessories, the Resorbable Mesh Pouch is to be filled with autograft by the clinician at the time of the procedure. Once filled, the Resorbable Mesh Pouch is to be closed using 2-0 Vicryl® sutures available to the clinician in the Operating Room (not provided with the

finished device). The filled, closed device is intended to be implanted into the posterolateral spine and pelvis.

The Resorbable Mesh Pouch is provided in individually sterile packaged units. The product is terminally sterilized by electron beam irradiation and validated to ensure a minimum Sterility Assurance Level (SAL) of 10^{-6}.

Intended Use/Indications for use

The Resorbable Mesh Pouch, once filled with autograft, 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 in the posterolateral spine and pelvis as a bone void filler and bone graft extender. The voids or gaps may be surgically created defects or the result of traumatic injury to the bone. Ultimately, the Resorbable Mesh Pouch will be resorbed.

Summary of Technological Characteristics

The Resorbable Mesh Pouch 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

The subject device is the same as the predicate device in terms of materials and manufacturing process of the PLGA mesh pouch. The subject device does not introduce a new worst case for biocompatibility and bacterial endotoxin. 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 was conducted and 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. A sterilization validation was performed and complies with *ISO 11137, Sterilization of Sterilization of Health Care Products – Radiation* to ensure a sterility assurance level (SAL) of 10^{-6}.

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 *Resorbable Mesh Pouch* is substantially equivalent to the cited legally marketed predicate.