September 27, 2023

SeaSpine Orthopedics Corporation
Cindy Toyama
Regulatory Affairs Specialist
5770 Armada Drive
Carlsbad, California 92008

Re: K232668
Trade/Device Name: Cove Strip, OsteoCove Strip
Regulation Number: 21 CFR 888.3045
Regulation Name: Resorbable Calcium Salt Bone Void Filler Device
Regulatory Class: Class II
Product Code: MQV
Dated: August 31, 2023
Received: September 1, 2023

Dear Cindy Toyama:

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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,

Sara S. Thompson -S

For

Jesse Muir, 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)*
K232668

Device Name
Cove Strip

Indications for Use *(Describe)*
Cove Strip is an implant intended to fill bony voids or gaps of the skeletal system (i.e., posterolateral spine and pelvis). These osseous defects are surgically created or the result of traumatic injury to the bone and are not intrinsic to the stability of the bony structure. Cove Strip resorbs and is replaced with bone during the healing process. Cove Strip must be used with autograft as a bone graft extender in the posterolateral spine and pelvis.

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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The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

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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)*
K232668

Device Name
OsteoCove Strip

Indications for Use *(Describe)*
OsteoCove Strip is an implant intended to fill bony voids or gaps of the skeletal system (i.e., posterolateral spine and pelvis). These osseous defects are surgically created or the result of traumatic injury to the bone and are not intrinsic to the stability of the bony structure. OsteoCove Strip resorbs and is replaced with bone during the healing process. OsteoCove Strip must be used with autograft as a bone graft extender in the posterolateral spine and pelvis.

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)

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510(k) Summary

K232668

Contact Details

Applicant Name: SeaSpine Orthopedics Corporation
Address: 5770 Armada Drive, Carlsbad CA
Phone number: (949) 855-7175
Fax number: (760) 683-6874

Contact Person: Cindy Toyama, Regulatory Affairs Specialist

Date Prepared: September 26, 2023

Device Name

Device/Trade Name: Cove Strip, OsteoCove Strip

Common Name: Bone Void Filler

Classification Name: Filler, Bone Void, Calcium Compound (21 CFR 888.3045)

Class: II

Product Code: MQV

Legally Marketed Predicate Device

510(k) Number	Product Code	Trade Name	Manufacturer
Primary Predicate Device			
K230486	MQV	Cove Strip, OsteoCove Strip	IsoTis OrthoBiologics, Inc.

Device Description

Cove Strip:

Cove Strip is comprised of a ceramic granule consisting of a ratio of 70:30 Beta-Tricalcium Phosphate (β-TCP): Hydroxyapatite (HA) combined with highly purified Type-1 collagen. The collagen scaffold contains ceramic granules throughout, providing osteoconductive substrates that support new bone formation. Cove Strip combined with autograft in a 1:1 ratio, is intended

to be placed in the posterolateral spine. The implant is provided sterile and non-pyrogenic for single use in a double blister tray configuration.

OsteoCove Strip:
OsteoCove Strip is comprised of a ceramic granule consisting of a ratio of 70:30 Beta-Tricalcium Phosphate (β-TCP): Hydroxyapatite (HA) combined with highly purified Type-1 collagen. The collagen scaffold contains ceramic granules throughout, providing osteoconductive substrates that support new bone formation. OsteoCove Strip combined with autograft in a 1:1 ratio, is intended to be placed in the posterolateral spine. The implant is provided sterile and non-pyrogenic for single use in a double blister tray configuration.

Indications for Use

Cove Strip:
Cove Strip is an implant intended to fill bony voids or gaps of the skeletal system (i.e., posterolateral spine and pelvis). These osseous defects are surgically created or the result of traumatic injury to the bone and are not intrinsic to the stability of the bony structure. Cove Strip resorbs and is replaced with bone during the healing process. Cove Strip must be used with autograft as a bone graft extender in the posterolateral spine and pelvis.

OsteoCove Strip:
OsteoCove Strip is an implant intended to fill bony voids or gaps of the skeletal system (i.e., posterolateral spine and pelvis). These osseous defects are surgically created or the result of traumatic injury to the bone and are not intrinsic to the stability of the bony structure. OsteoCove Strip resorbs and is replaced with bone during the healing process. OsteoCove Strip must be used with autograft as a bone graft extender in the posterolateral spine and pelvis.

Summary of Technological Characteristics

The subject device is similar to the cited predicate device in regard to components, device description, indications for use, device characteristics (i.e., design, materials, sterility, manufacturing, packaging, sterility, etc.), and performance. Compared to the predicate device, the subject device is longer; as such, the packaging was scaled accordingly. All materials, designs, and configurations are equivalent.

Summary of Non-Clinical Testing to Support Substantial Equivalence

The subject device is similar to the predicate device in terms of materials, manufacturing process, and intended use. Non-clinical testing was not performed on the subject device, as the subject device does not introduce a new worst case, for the following: biocompatibility and *in vivo* (animal) safety and performance.

Equivalency was established with the predicate device consisting of similar product sizing and packaging that allowed the adoption of the sterilization validation. Sterilization complies with I*SO 11135, Sterilization of health care products-Ethylene Oxide-Requirements* to ensure a sterility assurance level (SAL) of 10^{-6}.

The following verification and validation activities were evaluated for the subject device:

1. Design Verification

2. Ethylene Oxide (EO) Adoption
3. Limulus Amebocyte Lysate (LAL) Kinetic Turbidimetric Validation
4. Packaging Shipping Validation
5. Packaging Shelf Life Validation
6. Design (User) Validation
7. Process Performance Qualification

All activities were executed successfully to demonstrate substantial equivalence.

Clinical Testing

Not applicable. The 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.