August 21, 2023

SeaSpine Orthopedics Corporation
Cindy Toyama
Regulatory Affairs Specialist
2 Goodyear
Irvine, California 92618

Re: K230486
Trade/Device Name: Cove Strip
Regulation Number: 21 CFR 888.3045
Regulation Name: Resorbable Calcium Salt Bone Void Filler Device
Regulatory Class: Class II
Product Code: MQV
Dated: July 22, 2023
Received: July 24, 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 (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 -S

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)*

K230486

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.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

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:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

510(k) Summary

K230486

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: June 21, 2023

Device Name

Device/Trade Name: Cove 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			
K140375	MQV	MASTERGRAFT Putty	Medtronic Sofamor Danek USA, Inc.
Additional Predicate Device			
K063124	MQV	Integra MOZAIK™ Bone Regeneration Matrix – Strip*	Integra LifeSciences Corporation

**Since the most recently cleared 510(k) for the predicate device, Integra MOZAIK™ Osteoconductive Scaffold – Strip (K063124), under contractual agreements between IsoTis OrthoBiologics, Inc. and Integra LifeSciences Corporation, the device has been rebranded under a new trade name for IsoTis OrthoBiologics, Inc., and will herein be referred to as "IsoTis Mozaik Strip". IsoTis Mozaik Strip is legally manufactured by IsoTis OrthoBiologics, Inc.*

Device Description

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.

Indications for Use

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.

Summary of Technological Characteristics

The subject device is identical or similar to the cited predicate devices in regard to intended use/indications for use, device description, technological characteristics (i.e. design, materials, manufacturing, labeling, sterility, etc.), and non-clinical performance (i.e., *in vivo* performance (animal) study).

Summary of Non-Clinical Testing to Support Substantial Equivalence

Non-clinical testing performed on the subject device includes tests for biocompatibility and bacterial endotoxin to establish safety. Biocompatibility was performed in accordance with *ISO 10993-1, Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process*. Bacterial endotoxin testing complies with *AAMI ST72 Bacterial Endotoxins – Test Methods, Routine Monitoring, and Alternatives to Batch Testing*, *USP<85> Bacterial Endotoxin Test,* and *USP<161>, Medical Devices – Bacterial Endotoxin and Pyrogen Tests,* and has been validated ensure a BET limit of ≤20 EU/Device.

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

An *in vivo* (animal) study for safety and performance demonstrated comparable resorption, remodeling and rates of fusion when compared to a legally marked predicate. The study employed various analyses and endpoints were assessed at several time points. The subject device was also assessed per *ISO 10993-6:2016 Biological evaluation of medical devices – Part 6: Tests for local effects after implantation*.

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.