September 25, 2024

SeaSpine Orthopedics Corporation
Patrick Hughes
Regulatory Affairs Program Manager
5770 Armada Drive
Carlsbad, California 92008

Re: K242273
Trade/Device Name: Cove Putty, OsteoCove Putty
Regulation Number: 21 CFR 888.3045
Regulation Name: Resorbable Calcium Salt Bone Void Filler Device
Regulatory Class: Class II
Product Code: MQV
Dated: July 31, 2024
Received: August 1, 2024

Dear Mr. Hughes:

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.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

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,

JESSE MUIR -S

Digitally signed by JESSE MUIR -S
Date: 2024.09.25 10:59:17 -04'00'

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: 07/31/2026
See PRA Statement below.

510(k) Number *(if known)*
K242273

Device Name
Cove Putty, OsteoCove Putty

Indications for Use *(Describe)*
Cove 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. Cove Putty is hydrated with saline at the point-of-use. When used in intervertebral body fusion procedures, Cove Putty must be used as a bone graft extender with an intervertebral body fusion device cleared by FDA for use with a bone void filler.

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.

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510(k) Summary

Contact Details

Applicant Name: SeaSpine Orthopedics Corporation
Address: 5770 Armada Drive, Carlsbad CA 92008
Phone number: (352) 359-7940
Fax number: (760) 683-6874

Contact: Patrick Hughes, Regulatory Affairs Program Manager
Date Prepared: September 24, 2024

Subject Device

Device/Trade Name: Cove Putty, OsteoCove Putty
Common Name: Bone Void Filler
Classification Name: Filler, Bone Void, Calcium Compound (21 CFR 888.3045)
Class: II
Product Code: MQV

Predicate Devices

1. NuVasive AttraX Putty cleared per 510(k) submission K203714

Reference Devices

1. Cove Putty cleared per 510(k) submission K231030
2. SIGNAFUSE Putty cleared per 510(k) K233490

Device Description

Cove Putty is formulated into a putty which consists of a collagen scaffold containing ceramic granules and a resorbable polymer carrier throughout. The combined collagen and ceramic provide osteoconductive substrates that support new bone formation. Cove Putty 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 standard syringe.

Indications for Use

Cove 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. Cove Putty is hydrated with saline at the point-of-use. When used in intervertebral body fusion procedures, Cove Putty must be used as a bone graft extender with an intervertebral body fusion device cleared by FDA for use with a bone void filler.

Summary of Technological Characteristics

The subject device is identical to Cove Putty cleared per 510(k) submission K231030. The subject device is similar to the cited predicate NuVasive AttraX Putty and reference SIGNAFUSE Putty in regard to intended use, indications, and key technological characteristics (i.e., design, materials, manufacturing, labeling, sterility, etc.).

Summary of Non-Clinical Testing

Non-clinical testing originally submitted as part of 510(k) K231030 was performed on the subject device to establish biocompatibility bacterial endotoxin safety. A sterilization validation for the subject device was submitted as part of 510(k) K231030 to ensure a sterility assurance level (SAL) of 10^{-6}. An *in vivo* animal study for safety and performance submitted as part of 510(k) K231030 demonstrated Cove Putty functions as intended in terms of resorption, remodeling, and rates of fusion when compared to a legally marketed predicate. Expansion of the Cove Putty Indications for Use statement to employ the subject device in the intervertebral body space is supported by a clinical rationale included in the subject submission.

Conclusions

Subject Cove Putty is the same device as Cove Putty cleared per 510(k) submission K231030. Subject Cove Putty is substantially equivalent to cited predicate AttraX Putty as well as reference SIGNAFUSE Putty. Per testing previously submitted as part of 510(k) K231030, any differences in technological characteristics between the subject device, predicate AttraX Putty, and reference SIGNAFUSE Putty do not raise questions of safety and effectiveness. Based on the clinical rationale included in this submission and the establishment of substantial equivalence to cited predicates, Cove Putty may be indicated for use in intervertebral body fusion procedures as a bone graft extender with an intervertebral body fusion device cleared by FDA for use with a bone void filler.