May 21, 2025

Spinal Elements, Inc.
Cheryl Allen
Associate Director, Regulatory Affairs
3115 S. Melrose Suite 200
Carlsbad, California 92010

Re: K242527
Trade/Device Name: The Karma® Fixation System
Regulatory Class: Unclassified
Product Code: MRW
Dated: April 23, 2025
Received: April 23, 2025

Dear Cheryl Allen:

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,

Maziar Shah Mohammadi

For: Brent Showalter, Ph.D.
Assistant Director
DHT6B: Division of Spinal 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)*
K242527

Device Name
Karma® Fixation System

Indications for Use *(Describe)*
The Karma Fixation System is intended for bilateral facet stabilization for fusion as an adjunct to a 1-level interbody lumbar fusion from L1 to L5 with autogenous and/or allogenic bone graft. The Karma Fixation System must be accompanied by an FDA cleared intervertebral body fusion device implanted at the same spinal level. The Karma Fixation System is indicated for the treatment of patients with lumbar degenerative disc disease at a single level from L1 to L5 in skeletally mature patients who have failed conservative care.

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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"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
Karma® Fixation System

Date: May 13, 2025

I. SUBMITTER

Company Information:	Spinal Elements, Inc. 3115 Melrose Dr., Suite 200 Carlsbad, CA 92010
Contact Information:	Cheryl Allen Associate Director, 760-607-1840 callen@spinalelements.com

II. DEVICE

Proprietary Name	**Karma® Fixation System**
Common Name	Facet Fixation System
Device Classification	unclassified
Proposed Regulatory Class	unclassified
Device Product Code	MRW
Primary Predicate Device	zLOCK Lumbar Facet Fixation System (K240085)
Reference Device	Karma Fixation System (K180728 / K190289)

III. DEVICE DESCRIPTION

The Karma® Fixation System is a system that provides adjunctive fixation. The system consists of a PEEK band. The Karma band consists of a strap manufactured from PEEK compounded with 7.5% barium sulphate for radiopacity. The leading tip of the device is comprised of a spherical feature followed by a tapered neck to allow for an instrument to assist in advancing the strap around the bony structures to be secured. The spherical tip of the device contains a tantalum insert for visualization when fluoroscopic imaging is used. The device has teeth along its length that interact with a latching mechanism at the opposite end of the strap. The latch allows a loop created by feeding the strap through the latch to be made consecutively shorter or taut by continuing to pull the strap through the latch. Prior to creating the loop, the spherical tip of the device is cut off and discarded to allow for the strap to pass through the latch. The latch resists the lengthening of the loop due to forces that would pull the strap in the opposite direction, thereby securing the bony structures. Once the desired loop length is reached, the unneeded portion of the strap may be cut off and discarded. An instrument, Tensioner, is provided and can be used fully tension the implant.

IV. INDICATION FOR USE

The Karma Fixation System is intended for bilateral facet stabilization for fusion as an adjunct to a 1-level interbody lumbar fusion from L1 to L5 with autogenous and/or allogenic bone graft. The Karma Fixation System must be accompanied by an FDA cleared intervertebral body fusion device implanted at the same spinal level. The Karma Fixation System is indicated for the treatment of patients with lumbar degenerative disc disease at a single level from L1 to L5 in skeletally mature patients who have failed conservative care.

VII. TECHNOLOGICAL CHARACTERISTICS OF DEVICE

Karma Fixation System is identical to the reference device regarding device design, device description, technological characteristics (design, components, material, chemical composition, manufacturing, labeling, sterility, etc). The Karma Fixation System has similar indications to the primary predicate.

VIII. PERFORMANCE DATA

The subject device has the same performance characteristics as the previously cleared reference devices. Usability studies were conducted to evaluate the Karma Fixation System operating principle. Biomechanical cadaveric, Finite Element Analysis, cadaveric abrasion testing were also performed.

IX. CLINICAL DATA

Clinical performance data for intra-laminar placement was evaluated using CT evaluations at 12 and 24 months, adverse event data, and patient reported outcomes (Oswestry Disability Index and visual analog scale for back and leg pain).

X. SUBSTANTIAL EQUIVALENCE

Karma Fixation System has been found to be substantially equivalent to the predicate device with respect to intended use/indications for use, device description, technological characteristics and performance.