April 3, 2019

Spinal Elements Inc
Julie Lamothe, Ph.D., MBA
Vice President of Regulatory Affairs
3115 Melrose Drive, Suite 200
Carlsbad, California 92010

Re: K190289
Trade/Device Name: Karma® Fixation System
Regulation Number: 21 CFR 888.3010
Regulation Name: Bone fixation cerclage
Regulatory Class: Class II
Product Code: OWI
Dated: February 4, 2019
Received: February 11, 2019

Dear Dr. Lamothe:

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/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Ronald P. Jean -S

for Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
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)*
K190289

Device Name
Karma® Fixation System

Indications for Use *(Describe)*

The Karma® Fixation System is intended for use in cardiovascular surgery. The indications for use include cardiovascular surgery for closure of the sternum following sternotomy. The system is intended to provide temporary stabilization during the development of solid bony fusion.

The Karma® Fixation System is a temporary implant to be used in orthopedic surgery. The Karma® implant is a bony anchor designed to provide temporary stabilization of the spine for bony fusion or consolidation of a fracture. The Karma® Fixation System is designed for a posterior approach. The indications for use include the following applications:

1. Spinal trauma surgery: Karma® implants can be used in sublaminar wiring techniques;
2. Spinal degenerative surgery: Karma® implants may be used as an adjunct to spinal fusions with bone graft (autograft or allograft) at level(s) of use.

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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"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

510(k) Number: _____

Manufacturer Identification

Submitted By: Spinal Elements, Inc.
3115 Melrose Drive, Suite 200
Carlsbad, CA 92010
760-607-0121
760-607-0125 (fax)

Contact Information: Julie Lamothe
Spinal Elements, Inc.
3115 Melrose Drive, Suite 200
Carlsbad, CA 92010
760-607-1816
760-607-0125 (fax)
jlamothe@spinalelements.com

Date Prepared: February 4th, 2019

Device Identification

Proprietary Name	Karma® Fixation System
Common Name	Fixation System
Device Classification	21 CFR 888.3010
Device Regulation Name	Bone Fixation Cerclage
Proposed Regulatory Class	Class II
Device Product Code	OWI

Device Description

The Karma® Fixation System consists of a strap manufactured from PEEK conforming to ASTM F2026 compounded with 7.5% barium sulphate for radiopacity and Tantalum conforming to ASTM F560. 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 through or around the bony structures to be secured. Both the spherical tip and the head of the device contain a tantalum pin 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 taught 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 structures intended to be fixed. Once the desired loop length is reached, the unneeded portion of the strap may be cut off and discarded.

Indications for Use
The Karma® Fixation System is intended for use in cardiovascular surgery. The indications for use include cardiovascular surgery for closure of the sternum following sternotomy. The system is intended to provide temporary stabilization during the development of solid bony fusion.

The Karma® Fixation System is a temporary implant to be used in orthopedic surgery. The Karma® implant is a bony anchor designed to provide temporary stabilization of the spine for bony fusion or consolidation of a fracture. The Karma® Fixation System is designed for a posterior approach. The indications for use include the following applications:

1. Spinal trauma surgery: Karma® implants can be used in sublaminar wiring techniques;
2. Spinal degenerative surgery: Karma® implants may be used as an adjunct to spinal fusions with bone graft (autograft or allograft) at level(s) of use.

Substantial Equivalence
The subject device is substantially equivalent to the primary predicate device cleared in K180728.

Technological Characteristics
The subject device was established as substantially equivalent to another predicate device cleared by the FDA for commercial distribution in the Untied States. The subject device was shown to be substantially equivalent and have the same technological characteristics to its predicate device through comparison in areas including design, intended use, operating principle and function.

Performance Data
No additional testing was performed in support for this 510(k) Premarket Notification. An engineering rationale was provided to demonstrate substantial equivalence when compared to the predicate device

Conclusion
Based on the indication for use, technological characteristics, and comparison to predicate device, the Karma® Fixation System has been shown to be substantially equivalent to a legally marketed predicate device.