Spineology, Inc.
℅ Mr. Andrew Adams
Director of Regulatory Affairs
7800 3rd Street North, Suite 600
Saint Paul, Minnesota 55128

May 23, 2019

Re: K191091
Trade/Device Name: Rampart™ One Lumbar Interbody Fusion System
Regulation Number: 21 CFR 888.3080
Regulation Name: Intervertebral Body Fusion Device
Regulatory Class: Class II
Product Code: OVD
Dated: April 22, 2019
Received: April 24, 2019

Dear Mr. Adams:

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,

for CAPT Raquel Peat, PhD, MPH, USPHS
Director
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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K191091

Device Name
Rampart™ One Lumbar Interbody Fusion System

Indications for Use *(Describe)*
The standard and oblique Rampart One devices are integrated intervertebral body fusion devices indicated for intervertebral body fusion at one level or two contiguous levels in the lumbar spine from L2 to S1 in patients with degenerative disc disease (DDD) with up to Grade I spondylolisthesis at the involved level(s). DDD is defined as back pain of discogenic origin with degeneration of the disc confirmed by patient history and radiographic studies. These patients should be skeletally mature and have had six months non-operative treatment. The standard and oblique Rampart One devices are designed for use with autograft and/or allograft comprised of cancellous and/or corticocancellous bone graft.

The standard Rampart One device may be used with or without supplemental fixation using fixation systems cleared by FDA for use in the lumbar spine. When used without supplemental fixation, the standard Rampart One device must be used with four (4) screws.

The oblique Rampart One device must be used with two (2) screws and with supplemental fixation systems cleared by FDA for use in the lumbar spine.

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.

Spineology

510(k) Summary

Date Prepared: May 22, 2019

Submitter: Spineology, Inc.
7800 3rd Street North
Suite 600
Saint Paul, MN 55128

Establishment Registration Number: 2135156

Contact Person: Andrew Adams
Director of Regulatory Affairs
Phone: 651.256.8534
Fax: 651.256.8505
Email: aadams@spineology.com

Device Name and Classification

Trade Name:	Rampart™ One Lumbar Interbody Fusion System
Common Name:	Intervertebral fusion device with integrated fixation
Classification Name:	OVD
Regulatory Class:	Class II
Regulation Number:	21 CFR 888.3080
Panel:	Orthopedic

Predicate Device

Primary: K180002 Rampart™ One Lumbar Interbody Fusion Device (Spineology Inc.)

A. Purpose of Premarket Notification

The purpose of this premarket notification is to obtain FDA clearance to introduce a new Implant Inserter and modified Inserter Guides to the Rampart One Lumbar Interbody Fusion System. The subject Implant Inserter provides an alternative design for ease of use based on user feedback. While previously classified as Class I devices, the Inserter Guides were modified to interface with the new Implant Inserter and are presented as Class II devices within this submission as they are unique to the implantation of the Rampart One Implant.

B. Device Description

Rampart One implants are intervertebral body fusion devices for use with bone graft in the intervertebral disc space to stabilize spinal segments as an adjunct to fusion. These devices are manufactured from PEEK-OPTIMA HA Enhanced (spacer), titanium alloy (face plate), and tantalum (radiopaque markers) materials. Rampart One devices incorporate integrated fixation in the form of titanium alloy screws. Rampart One devices are provided in standard and oblique configurations. The standard device accommodates four screws and the oblique device accommodates two screws. In each device, the screws are inserted through the anteriorly-located face plate into the adjacent vertebral bodies. Rampart One devices are provided in various heights and lordotic angles and contain a hollow core to receive autograft and/or allograft comprised of

cancellous and/or corticocancellous bone graft. Placement is achieved with an insertion instrument that allows for manipulation of the implant in the intervertebral disc space.

C. Indications for Use

The standard and oblique Rampart One devices are integrated intervertebral body fusion devices indicated for intervertebral body fusion at one level or two contiguous levels in the lumbar spine from L2 to S1 in patients with degenerative disc disease (DDD) with up to Grade I spondylolisthesis at the involved level(s). DDD is defined as back pain of discogenic origin with degeneration of the disc confirmed by patient history and radiographic studies. These patients should be skeletally mature and have had six months non-operative treatment. The standard and oblique Rampart One devices are designed for use with autograft and/or allograft comprised of cancellous and/or corticocancellous bone graft.

The standard Rampart One device may be used with or without supplemental fixation using fixation systems cleared by FDA for use in the lumbar spine. When used without supplemental fixation, the standard Rampart One device must be used with four (4) screws.

The oblique Rampart One device must be used with two (2) screws and with supplemental fixation systems cleared by FDA for use in the lumbar spine.

D. Comparison to Predicate Device

When compared to the predicate device, the new Implant Inserter and modified Inserter Guides have the same or equivalent:

- Intended Use
- Indications for Use
- Fundamental Scientific Technology
- Principle of Operation
- Primary Design Features
- Materials of Construction
- Function / Performance
- Risk Profile

E. Non-Clinical Testing

Design verification testing was conducted to support the new Implant Inserter and modified Inserter Guides confirming function and performance in simulated use.

- A review of the design changes was performed and confirmed that these modifications do not alter the intended use of the instruments or present new technological characteristics.
- The design changes do not alter the primary control mechanism or operating principle of the instruments.
- The instrument interface with the Rampart One Implant remains unchanged.
- A risk assessment was performed and confirmed that the modifications to the instruments do not alter the risk profile for the device or present new issues of safety or effectiveness when compared to the predicate device.

F. Conclusion

Based on the intended use, technological characteristics, and comparison to the predicate device, Spineology has demonstrated that the new Rampart One Implant Inserter and modified Inserter Guides have been shown to be substantially equivalent to the legally marketed predicate device.