August 23, 2019

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

Re: K192047
  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: July 29, 2019
  Received: July 31, 2019

Dear Andrew 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/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.


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,

David Hwang -S

For Melissa Hall, M.S.
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
Indications for Use

K192047

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 devices with 8° and 12° lordotic angles may be used with or without supplemental fixation using a fixation system cleared by FDA for use in the lumbar spine. When used without supplemental fixation, the standard Rampart One devices with 8° and 12° lordotic angles must be used with four (4) screws. The standard Rampart One devices with 16° and 20° lordotic angles must be used with four (4) screws and a supplemental fixation system cleared by FDA for use in the lumbar spine.

The oblique Rampart One devices must be used with two (2) screws and a supplemental fixation system 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.

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
Papworth 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."

FORM FDA 3881 (7/17)
A. Purpose of Premarket Notification
The purpose of this premarket notification is to obtain FDA clearance for a line extension of Implants with increased lordosis to the Rampart™ One Lumbar Interbody Fusion System. The subject Implants provide additional lordosis to accommodate individual pathology and anatomical conditions. This submission also includes Class II surgical instruments unique to the implantation of the device.

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 devices with 8° and 12° lordotic angles may be used with or without supplemental fixation using a fixation system cleared by FDA for use in the lumbar spine. When used without supplemental fixation, the standard Rampart One devices with 8° and 12° lordotic angles must be used with four (4) screws. The standard Rampart One devices with 16° and 20° lordotic angles must be used with four (4) screws and a supplemental fixation system cleared by FDA for use in the lumbar spine.

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

D. **Comparison to Predicate Devices**
When compared to the predicate devices, the subject Implants and surgical instruments 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**
Non-clinical testing was conducted to support the subject Implants and surgical instruments confirming function and performance.

- A review of the design changes was performed and confirmed that these modifications do not alter the intended use or present new technological characteristics.
- The design changes do not alter the primary control mechanism or operating principle.
- Benchtop mechanical ASTM testing and comparison confirmed that the subject Implants perform as intended in comparison to the primary predicate device.
- A risk assessment was performed and confirmed that the modifications introduced do not alter the risk profile for the device or present new issues of safety or effectiveness when compared to the predicate devices.
F. Conclusion

Based on the intended use, technological characteristics, and comparison to the predicate devices, Spineology has demonstrated that the subject Rampart One Implants and Class II surgical instruments have been shown to be substantially equivalent to the legally marketed predicate devices.