



Food and Drug Administration  
10903 New Hampshire Avenue  
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Silver Spring, MD 20993-0002

Spineology, Inc.  
Jacqueline Hauge  
Regulatory Affairs Manager  
7800 3rd Street N., Suite 600  
St. Paul, Minnesota 55128-5455

July 24, 2017

Re: K171724

Trade/Device Name: Rampart™ L Lumbar Interbody Fusion Device  
Regulation Number: 21 CFR 888.3080  
Regulation Name: Intervertebral body fusion device  
Regulatory Class: Class II  
Product Code: MAX  
Dated: June 26, 2017  
Received: June 27, 2017

Dear Ms. Hauge:

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. 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); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address

<http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>. 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 the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address

<http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely,

**Mark N. Melkerson -S**

Mark N. Melkerson  
Director  
Division of Orthopedic Devices  
Office of Device Evaluation  
Center for Devices and  
Radiological Health

Enclosure

## Indications for Use

510(k) Number (if known)

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Device Name

Rampart™ L Lumbar Interbody Fusion  
Device

Indications for Use (Describe)

Rampart™ L is an intervertebral body fusion device 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 1 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 of non-operative studies. Rampart™-L is designed for use with autograft as an adjunct to fusion and is intended for use with supplemental fixation systems cleared by the 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.

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**Date Prepared:** June 09, 2017

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**Submitter:** Spineology Inc.  
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Establishment Registration Number: 2135156

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#### **Device Name and Classification**

**Trade Names:** Rampart™ L Lumbar Interbody Fusion System  
**Common Name:** Intervertebral body fusion device  
**Product Code:** MAX  
**Regulatory Class:** Class II  
**Regulation Number:** 21 CFR 888.3080  
**Panel:** Orthopedic

#### **Predicate Device**

**Primary:** K133371 Rampart™ L Lumbar Interbody Fusion Device (Spineology Inc.)

#### **A. Purpose of Submission**

Currently, the FDA-cleared Rampart™-L system includes 12mm wide implantable devices. The purpose of this submission is for the expansion of the Rampart™-L product line to include 18mm and 22mm wide implantable devices. All other primary technological characteristics of the subject 18mm and 22mm devices remain unchanged from the 12mm predicate device.

#### **B. Device Description**

Rampart™-L is an intervertebral body fusion device for use with autogenous bone graft in the intervertebral disc space to stabilize spinal segments as an adjunct to fusion. The device is made of PEEK-OPTIMA LT1 with Tantalum markers and is provided in various configurations and heights, containing a hollow core to receive bone autograft. Placement is achieved with an insertion instrument that allows for manipulation of the implant in the intervertebral disc space.

#### **C. Indications for Use**

Rampart™-L is an intervertebral body fusion device 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 1 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 of non-operative studies. Rampart™-L is designed for use with autograft as an adjunct to fusion and is intended for use with supplemental fixation systems cleared by the FDA for use in the lumbar spine.

#### **D. Comparison to Predicate**

When compared to the predicate device, the subject Rampart™-L device has the same or equivalent:

- Intended Use
- Indications for Use
- Fundamental Scientific Technology
- Principle of Operation
- Device Design
- Materials of Construction
- Lengths
- Heights

#### **E. Non-Clinical Testing**

New performance testing was not performed for the subject 18mm and 22mm Rampart™-L devices. In order to confirm the safety and effectiveness of the subject 18mm and 22mm Rampart™-L devices as well as their substantial equivalence to the predicate 12mm Rampart™-L device, Spineology conducted a thorough assessment which included the following activities:

- Comparison of intended use
- Comparison of the technological characteristics; including primary design features and materials of construction
- Comparison of the areas and volume; including through growth area, surface contact area, and bone graft volume
- Review of predicate performance data
- Review of predicate risks and risk mitigation measures

Based on this assessment, Spineology confirmed that the subject 18mm and 22mm Rampart™-L devices are substantially equivalent to the predicate device, do not represent a new worst-case device configuration when compared to the predicate device, and the predicate performance data and risk mitigation measures support the safe and effective use of these devices.

#### **F. Conclusion**

Based on the same indications for use, similar technological characteristics, and comparison to the predicate device, the 18mm and 22mm Rampart™-L devices have been shown to be substantially equivalent to the legally marketed predicate device.