



Food and Drug Administration  
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Silver Spring, MD 20993-0002

Spineology, Incorporated  
Ms. Jacqueline Hauge  
Regulatory Affairs Manager  
7800 3rd Street North, Suite 600  
St. Paul, Minnesota 55128

February 4, 2016

Re: K153082

Trade/Device Name: Rampart A Lumbar Interbody Fusion Device  
Regulation Number: 21 CFR 888.3080  
Regulation Name: Intervertebral body fusion device  
Regulatory Class: Class II  
Product Code: MAX  
Dated: October 22, 2015  
Received: October 23, 2015

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 Parts 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" (21CFR 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 yours,

**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)  
K153082

Device Name  
Rampart A Lumbar Interbody Fusion Device

### Indications for Use (Describe)

Rampart A 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 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 of non-operative treatment.

Rampart A 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.

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## 510(k) Summary

**Date Prepared:** October 22, 2015

**Applicant:** Spineology, Inc.  
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### Device Name and Classification

Trade Name: Rampart A Lumbar Interbody Fusion Device

Regulation Name: Intervertebral body fusion device

Regulation Number: 21 CFR 888.3080

Product Code: MAX

Regulatory Class: Class II

510(k) Review Panel: Orthopedic

### Predicate Devices

#### Primary Predicate

K123652 Spineology PEEK Lumbar Interbody Fusion Device

#### Additional Predicates

K132053 Rampart O, Rampart T Lumbar Interbody Fusion Device

K121129 Spineology PEEK Lumbar Interbody Fusion Device

#### Reference Device

K072253 SynFix-LR (Synthes Spine)

### Purpose of Submission

The purpose of this submission is to introduce the Rampart A Lumbar Interbody Fusion Device, a modified version of Spineology's previously cleared interbody fusion devices designed to accommodate anatomical features conducive to anterior or anterolateral placement within the intervertebral disc space.

**Device Description**

Rampart A implants are intervertebral body fusion devices for use with autogenous bone graft in the intervertebral disc space to stabilize spinal segments as an adjunct to fusion. These devices are made of PEEK-OPTIMA LT1 with Tantalum markers and are 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.

**Indications for Use**

Rampart A 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 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 of non-operative treatment.

Rampart A 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.

**Comparison to Predicate**

When compared to the predicate devices, Rampart A has the same:

- Intended Use
- Technological Characteristics
- Operating Principle
- Design Features
- Materials of Construction
- Packaging Materials
- Method of Sterilization
- Sterility Assurance Level (SAL)
- Shelf Life

**Summary of Performance and Biological Testing**

No performance testing was required for this change. An engineering rationale, including a finite element analysis (FEA) to compare the Rampart A to the existing predicate testing (conducted in accordance with ASTM F2077) supported the substantial equivalence of the Rampart A device.

Because the materials of construction remain unchanged from the predicate devices, the existing biological data remain valid and no new biocompatibility testing was required for this change.

**Conclusion**

Spineology has demonstrated that Rampart A devices are substantially equivalent to the predicate devices. The fundamental scientific principle, technological characteristics, and intended use are unchanged from the predicate devices.