



Food and Drug Administration  
10903 New Hampshire Avenue  
Document Control Center – WO66-G609  
Silver Spring, MD 20993-0002

Spineology, Incorporated  
Ms. Karen Roche  
Vice President, Operations & Technology  
7800 Third Street North, Suite 600  
Saint Paul, Minnesota 55128

July 22, 2015

Re: K151020  
Trade/Device Name: Rampart™ T Interbody Fusion System  
Regulation Number: 21 CFR 888.3080  
Regulation Name: Intervertebral body fusion device  
Regulatory Class: Class II  
Product Code: MAX  
Dated: June 24, 2015  
Received: June 24, 2015

Dear Ms. Roche:

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" (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)

K151020

Device Name

Rampart™-T Interbody Fusion System

Indications for Use (Describe)

Rampart-T implants are 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 of non-operative treatment.

Rampart-T implants are designed for use with autograft to facilitate fusion and are 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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## 510(k) Summary

### I. SUBMITTER

Spineology Inc.  
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Saint Paul, MN 55128

Phone: 651.256.8500

Fax: 651.256.8505

Contact Person: Karen Roche

Date Prepared: July 15, 2015

### II. DEVICE

Name of Device: Rampart™-T Interbody Fusion System

Common Name or usual name: Intervertebral fusion device with bone graft, lumbar

Classification Name: Intervertebral body fusion device (21 CFR §888.3080)

Regulatory Class: Class II

Product Code: MAX

### III. PREDICATE DEVICE

Spineology PEEK LIFD K110933 (Primary Predicate), K111880, K132053, K113030  
(Additional Predicates)

### IV. DEVICE DESCRIPTION

The Spineology Rampart™-T Interbody Fusion implant is a tapered version of the predicate Spineology PEEK Crescent implant. The subject and predicate devices are composed of PEEK - OPTIMA® LT1 (polyetheretherketone). The subject device and the primary predicate are both manufactured as a curved (crescent) shape and contain two areas for the placement of autograft. Additionally, the subject and predicate devices contain tantalum alloy markers to assist in device placement through intraoperative imaging. The devices all have a toothed fish-scale style anti-backout design on the surfaces that interface with the vertebral body endplates. The subject device is tapered at its leading end for ease of initial implantation and will maintain the same 6 degree lordotic angle to accommodate a suitable fit in the disc space.

## **V. INDICATIONS FOR USE**

Rampart-T implants are 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 of non-operative treatment.

Rampart-T implants are designed for use with autograft as an adjunct to fusion and are intended for use with supplemental fixation systems cleared by the FDA for use in the lumbar spine.

## **VI. COMPARISON OF TECHNOLOGICAL FEATURES WITH THE PREDICATE DEVICE**

The Spineology Rampart-T Interbody Fusion Implant shares the same indications, materials, function, and performance as the predicate implants.

## **VII. PERFORMANCE DATA**

The Rampart-T Interbody Fusion System has previously undergone performance testing. The testing was performed in accordance with the FDA's guidance titled: *Class II Special Controls Guidance Document: Intervertebral Body Fusion Device*. Additionally preclinical testing was performed in accordance with ASTM F2077 and ASTM F2267. This testing included static compression shear, shear, and dynamic axial and shear compression, subsidence and expulsion. This testing has been previously submitted and reviewed by the FDA.

## **VIII. CONCLUSIONS**

The Rampart-T Interbody implant is substantially equivalent to the cited predicate implants. This conclusion is based on a comparison of intended use, materials, technological features, and comparative performance testing.