DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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

July 14, 2016

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

Re: K160906
Trade/Device Name: Rampart™ O Lumbar Interbody Fusion Device, Rampart™ T Lumbar Interbody Fusion Device, 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: April 15, 2016
Received: April 18, 2016

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 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,

Lori A. Wiggins -S

for

Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K160906

Device Name
Rampart™ O Lumbar Interbody Fusion Device
Rampart™ T Lumbar Interbody Fusion Device
Rampart™ A Lumbar Interbody Fusion Device

Indications for Use *(Describe)*
Rampart™ O, Rampart™ T, and Rampart™ A 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 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 treatment.

Rampart™ O, Rampart™ T, and Rampart™ A implants are designed for use with autograft and/or allograft comprised of cancellous and/or corticocancellous bone graft as an adjunct to 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.

Spineology

510(k) Summary

Date Prepared: June 30, 2016

Submitter: Spineology Inc.
7800 3rd Street North
Suite 600
Saint Paul, MN 55128
Establishment Registration Number: 2135156

Contact Person: Jacqueline A. Hauge
Regulatory Affairs Manger
Phone: 651.256.8534
Fax: 651.256.8505
Email: jhauge@spineology.com

Device Name and Classification

Trade Name:	Rampart™ O Lumbar Interbody Fusion Device Rampart™ T Lumbar Interbody Fusion Device Rampart™ A Lumbar Interbody Fusion Device
Common Name:	Spinal implant
Classification Name:	Intervertebral body fusion device
Product Codes:	MAX
Regulatory Class:	Class II
Regulation Number:	21 CFR 888.3080
Panel:	Orthopedic

Predicate Devices

Primary:	K150788	Talos Intervertebral Body Fusion Devices (Meditech Spine, LLC)
Additional:	K132053	Rampart O, Rampart T Lumbar Interbody Fusion Device
	K153082	Rampart A Lumbar Interbody Fusion Device

Purpose

The purpose of this 510(k) is to obtain clearance to expand the current indications for use to include use of either autograft and/or allograft as a substitute/addition to autologous bone.

Device Description

Rampart O, Rampart T, and Rampart A 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 made of PEEK-OPTIMA LT1 with titanium or tantalum markers and are provided in various configurations and heights, containing a hollow core to receive bone autograft and/or allograft. Placement is achieved with an insertion instrument that allows for manipulation of the implant in the intervertebral disc space.

Indications for Use

Rampart O, Rampart T, and Rampart A 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 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 treatment.

Rampart O, Rampart T, and Rampart A implants are designed for use with autograft and/or allograft comprised of cancellous and/or corticocancellous bone graft as an adjunct to fusion and are intended for use with supplemental fixation systems cleared by the FDA for use in the lumbar spine.

Technological Characteristics

The technological characteristics of Rampart O, Rampart T, and Rampart A are identical to the additional predicate devices in terms of intended use and design. The indications for use are similar. The addition of allograft comprised of cancellous and/or corticocancellous bone graft to Rampart O, Rampart T, and Rampart A does not increase the risks associated with use of the device.

Non-Clinical Testing

There have been no design changes made to the Rampart O, Rampart T, and Rampart A devices to support use of allograft material. No design changes were made to the existing devices, nor were any new components added to these systems; therefore, mechanical testing was not required or performed to support substantial equivalence.

Bacterial Endotoxin testing (BET), also known as the Limulus amebocyte lysate (LAL) test, was performed per ANSI/AAMI/ST72 to a limit of <20 EU/Device.

Clinical Testing

A review of published clinical data for lumbar intervertebral body fusion devices similar to the Rampart O, Rampart T, and Rampart A devices was provided in support of this application. The published clinical outcomes demonstrate that the use of allograft in interbody fusion procedures to treat patients with degenerative disc disease, as defined above, pose no new risks to patients. No design changes were made to the exiting devices, nor were any new components added to these systems; therefore, clinical testing was not required or performed to support substantial equivalence.

Conclusion

The Spineology Rampart O, Rampart T, and Rampart A devices have the same intended use, technological characteristics, design, and principles of operation as their predicate devices; as well as similar indications for use. The clinical literature review presented in this application supports a substantial equivalence determination of the Rampart O, Rampart T, and Rampart A devices.