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

March 8, 2017

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

Re: K163409
Trade/Device Name: Rampart™ T Lumbar Interbody Fusion Device
Regulation Number: 21 CFR 888.3080
Regulation Name: Intervertebral Body Fusion Device
Regulatory Class: Class II
Product Code: MAX
Dated: February 2, 2017
Received: February 3, 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

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)*
K163409

Device Name
Rampart T™ Lumbar Interbody Fusion Device

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 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 T 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.

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
Paperwork 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."

Spineology

510(k) Summary

Date Prepared: February 2, 2017

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

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

Device Name and Classification

Trade Name:	Rampart™ T 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:	K151020	Rampart™ T Lumbar Interbody Fusion Device
Additional:	K160906	Rampart™ T, Rampart™ O, Rampart™ A Lumbar Interbody Fusion Device

I. Purpose

The purpose of this submission is to obtain FDA clearance for the expanded indications for use statement to allow optional use of allograft comprised of cancellous and/or cortical cancellous bone graft as an adjunct to fusion.

II. Device Description

Rampart T 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. 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 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.

III. 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 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 T 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.

IV. Non-Clinical Testing

There have been no design changes made to the Rampart T device to support the use of allograft material; therefore, non-clinical testing was not required to demonstrate substantial equivalence. Bacterial endotoxin testing (BET), also known as limulus amebocyte lysate (LAL) testing, was conducted in accordance with ANSI/AAMI/ST72:2011.

V. Clinical Testing

A review of published clinical data for lumbar intervertebral body fusion devices similar to the Rampart T device 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 existing device, nor were any new components added to this system to support the use of allograft material; therefore, clinical testing was not required or performed to demonstrate substantial equivalence.

VI. Technological Characteristics

The Rampart T device has the same primary technological characteristics, including design and materials, as the predicate device. The fundamental scientific technology remains unchanged.

VII. Conclusion

The Rampart T device has the same intended use, technological characteristics, and principle of operation as the predicate devices. The clinical literature review presented in this application supports the expansion of the indications for use statement to include the optional use of allograft bone graft as an adjunct to fusion and a substantial equivalence determination of the Rampart T Lumbar Interbody Fusion Device as compared to the predicate devices.