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

October 18, 2016

Spineology Inc.
Ms. Karen Roche
VP, Operations & Technology
7800 Third Street North, Suite 600
Saint Paul, Minnesota 55128

Re: K160074
Trade/Device Name: Rampart™ D Lumbar Interbody Fusion Device
Regulation Number: 21 CFR 888.3080
Regulation Name: Intervertebral body fusion device
Regulatory Class: Class II
Product Code: MAX
Dated: September 7, 2016
Received: September 8, 2016

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 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,

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)*
K160074

Device Name
Rampart™ D Lumbar Interbody Fusion Device

Indications for Use *(Describe)*

The Rampart™ D Lumbar Interbody Fusion Device is indicated for intervertebral body fusion at one level or two contiguous levels in the lumbar spine from L2 to L5 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. The Rampart™ D device is designed for use with autograft and/or allograft comprised of cancellous and/or corticocancellous bone graft 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

Applicant:	Spineology Inc. 7800 3rd Street N., Suite 600 Saint Paul, MN 55128-5455 Phone: 651-256-8500 Fax: 651-256-8505	
Contact Person:	Karen Roche	
Date Prepared:	October 17, 2016	
Trade Name:	Rampart™ D Lumbar Interbody Fusion Device	
Common Name:	Interbody Spacer	
Product Classification and Name:	21 CFR § 888.3080 - Intervertebral body fusion device (Class II, Special Controls)	
Product Code:	MAX - Intervertebral Fusion Device With Bone Graft, Lumbar	
Predicate Device(s):	Primary Predicate:	**Rampart™L** (K133371); Spineology Inc.
	Additional Predicates:	1. **Interfuse L** (K131540); Vertebral Technologies, Inc. 2. **Elite L** Expandable Lumbar Fusion System (K150954); Innova Spinal Technologies, LLC
Reference Device:	OptiMesh (K014200); Spineology Inc.	
Device Description:	The Rampart™D Lumbar Interbody Fusion Device is an intervertebral implant designed to provide mechanical support within the intradiscal space as an adjunct to fusion. The device is made of PEEK-OPTIMA® LT-1, titanium alloy, polyethylene terephthalate (PET), and tantalum markers. It is available in varying lengths and heights with two lordotic configurations, and is provided sterile. It is designed with a porous central cavity for graft containment. The device features a rounded nose to aid implant insertion and includes ridged teeth to resist migration.	
Indications for Use:	The Rampart™D Lumbar Interbody Fusion Device is indicated for intervertebral body fusion at one level or two contiguous levels in the lumbar spine from L2 to L5 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. The Rampart™D device is designed for use with autograft and/or allograft comprised of cancellous and/or corticocancellous bone graft as an adjunct to fusion and is intended for use with supplemental fixation systems cleared by the FDA for use in the lumbar spine.
Purpose of this 510(k):	To receive FDA clearance to market the Rampart™D Lumbar Interbody Fusion Device in the US.
Summary of Technological Characteristics:	The Rampart™D Lumbar Interbody Fusion Device and the predicates share some technological characteristics, including materials of construction, comparable profile, dimensions and lordotic angles, serrated surfaces for endplate contact, similar graft containment areas and graft volume capacities. The reference device shares the same material and design features for use in graft containment.
Testing	Non-clinical testing was performed according to ASTM F2077 (static and dynamic axial compression and compression shear), ASTM F2267 (subsidence) and expulsion testing. Particulate analysis, bench-top and cadaveric implantation evaluations and load sharing tests were completed. All testing was conducted on worst case configurations for both sizing and recommended graft fill. Existing biological data on device materials was used to support the performance and biological safety of the device. Patient-level clinical data that was supplemented with a literature review was also provided to support the substantial equivalence of the subject device.
Conclusion:	The Rampart D device has the same intended use and Indications for Use statement as the predicate devices identified. The differences in technological characteristics between Rampart D and the predicate devices do not raise different safety or effectiveness questions. Non-clinical and clinical testing demonstrates substantial equivalence to legally marketed predicate devices when used under the labeled conditions.