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

May 8, 2017

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

Re: K163670
Trade/Device Name: Rampart One Lumbar Interbody Fusion Device
Regulation Number: 21 CFR 888.3080
Regulation Name: Intervertebral Body Fusion Device
Regulatory Class: Class II
Product Code: OVD
Dated: April 10, 2017
Received: April 11, 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)*

K163670

Device Name
Rampart One Lumbar Interbody Fusion Device

Indications for Use *(Describe)*

The standard and oblique Rampart One devices are integrated 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 non-operative treatment.

The standard and oblique Rampart One devices are designed for use with autograft and/or allograft comprised of cancellous and/or corticocancellous bone graft and are intended for use with supplemental fixations systems cleared by 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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Spineology

510(k) Summary

Date Prepared: May 3, 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
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Email: jhauge@spineology.com

Device Name and Classification

Trade Name:	Rampart One Lumbar Interbody Fusion Device
Common Name:	Intervertebral fusion device with integrated fixation
Product Codes:	OVD
Regulatory Class:	Class II
Regulation Number:	21 CFR 888.3080
Panel:	Orthopedic

Predicate Devices

Primary:	K153082	Rampart A Lumbar Interbody Fusion Device (Spineology Inc.)
Additional:	K111880	Rampart P Lumbar Interbody Fusion Device (Spineology Inc.)
	K160906	Rampart A, O, T Lumbar Interbody Fusion Devices (Spineology Inc.)
	K150321	EVOS Lumbar Interbody Fusion Device (Cutting Edge Spine, LLC)
	K072253	SynFix LR (Synthes Spine)
	K163543	Durango Stand-Alone ALIF System (Biomet Spine)

I. Purpose

The purpose of this premarket notification is to obtain initial 510(k) clearance of Spineology's Rampart One Lumbar Interbody Fusion Device.

II. Submission History

There have been no prior submissions submitted to FDA for the Rampart One Lumbar Interbody Fusion Device.

III. Device Description

Rampart One 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 manufactured from PEEK-OPTIMA HA Enhanced (spacer), titanium alloy (face plate), and tantalum (radiopaque markers) materials. Rampart One devices incorporate integrated fixation in the form of titanium alloy screws. Rampart One devices are provided in standard and oblique configurations. The standard device accommodates four screws and the oblique device accommodates two screws. In each device the screws are inserted through the anteriorly-located face plate into the adjacent vertebral bodies. Rampart One devices are provided in various heights and lordotic angles and contain a hollow core to receive 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.

IV. Indications for Use

The standard and oblique Rampart One devices are integrated 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 non-operative treatment.

The standard and oblique Rampart One devices are designed for use with autograft and/or allograft comprised of cancellous and/or corticocancellous bone graft and are intended for use with supplemental fixation systems cleared by FDA for use in the lumbar spine.

V. Comparison to Predicate

When compared to the predicate devices, Rampart One Lumbar Interbody Fusion Device has the same or similar:

- Intended Use
- Indications for Use
- Fundamental Scientific Technology
- Principle of Operation
- Biological Safety
- Base Materials
- Size Offering

VI. Non-Clinical Testing

The following mechanical testing was conducted in accordance with FDA's Class II Special Controls Guidance Document: Intervertebral Fusion Device (2007) and applicable American Society for Testing and Materials (ASTM) standards:

ASTM F2077

- Static and Dynamic Compression
- Static and Dynamic Compression Shear

ASTM F2267

- Subsidence

ASTM F543-13

- Axial Pullout

Anti-Screw Backout
Expulsion
Bacterial endotoxin testing (BET) was conducted in accordance with ANSI/AAMI ST-72:2011.

VII. Conclusion

Spineology has demonstrated that the Rampart One Lumbar Interbody Fusion Device is substantially equivalent to the predicate devices.