April 25, 2018

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

Re: K180002
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: March 23, 2018
Received: March 26, 2018

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.

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.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Vincent J. Devlin -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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K180002

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.

The standard Rampart One device may be used with or without supplemental fixation using fixation systems cleared by FDA for use in the lumbar spine. When used without supplemental fixation, the standard Rampart One device must be used with four (4) screws.

The oblique Rampart One device must be used with two (2) screws and with supplemental fixation 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.

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Spineology

510(k) Summary

Date Prepared: April 19, 2018

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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Device Name and Classification

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

Predicate Devices

Primary:	K163670	Rampart™ One Lumbar Interbody Fusion Device (Spineology Inc.)
Additional:	K150673	SYNFIX™ Evolution Secured Spacer System (Synthes Spine)

A. Purpose of Submission

The purpose of this submission is to expand the indications for use statement to allow the option to use the standard Rampart One implantable device as a stand-alone Anterior Lumbar Interbody Fusion (ALIF) device (without supplemental fixation systems cleared by FDA for use in the lumbar spine).

B. 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.

C. 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.

The standard Rampart One device may be used with or without supplemental fixation using fixation systems cleared by FDA for use in the lumbar spine. When used without supplemental fixation, the standard Rampart One device must be used with four (4) screws.

The oblique Rampart One device must be used with two (2) screws and with supplemental fixation systems cleared by FDA for use in the lumbar spine.

D. Comparison to Predicate Device

There have been no design changes to the standard and oblique Rampart One devices since there last clearance; therefore, when compared to the predicate device, the Rampart One Lumbar Interbody Fusion Device has the same:

- Intended Use
- Indications for Use
- Fundamental Scientific Technology
- Principle of Operation
- Materials
- Biocompatibility
- Size Offering

E. Non-Clinical Testing

New performance testing was not performed or required to support the modification to the indications for use statement. The initial performance testing conducted for the Rampart One device remains valid and the data obtained provides reasonable assurance of the safety and effectiveness of the Rampart One device when used within the context and limitations of the intended use.

The previously conducted performance testing established conformance to the following:

ASTM F2077
- Static and Dynamic Compression
- Static and Dynamic Compression Shear

ASTM 2267
- Subsidence

ASTM F543-13
- Axial Pullout

Anti-Screw Backout
Expulsion
Bacterial Endotoxin Testing (BET) conducted in accordance with ANSI/AAMI FT-72:2011

F. Clinical Testing

A review of published clinical data for stand-alone anterior lumbar intervertebral body fusion devices with integrated fixation was provided in support of this application. The published clinical outcomes demonstrate that the use of such devices to treat patients with degenerative disc disease, as defined above, poses no new risks to patients. No new components were added to the Rampart One system, nor were any substantive design changes made to the existing devices; therefore, clinical testing was not required or performed to support substantial equivalence.

G. Conclusion

Based on the indications for use, technological characteristics, comparison to the predicate devices, and supportive literature review, Spineology has demonstrated that the Rampart One Lumbar Interbody Fusion Device is substantially equivalent to the legally marketed predicate device.