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

January 27, 2017

Spineology Inc.
Ms. Jacqueline Hauge
Regulatory Affairs Manager
7800 3rd Street North, Suite 600
St. Paul, Minnesota 55127

Re: K162879
Trade/Device Name: Elite™ Expandable Interbody Fusion Device
Regulation Number: 21 CFR 888.3080
Regulation Name: Intervertebral Body Fusion Device
Regulatory Class: Class II
Product Code: MAX
Dated: December 21, 2016
Received: December 22, 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 (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)*

K162879

Device Name

Elite™ Expandable Interbody Fusion Device

Indications for Use *(Describe)*

Elite™ Expandable 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.

Elite™ Expandable 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.

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Spineology

510(k) Summary

Date Prepared: December 21, 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:	Elite™ Expandable 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:	K133459	Elite™ Interbody Fusion Device (Innova Spinal Technologies, LLC)
Additional:	K160906	Rampart™ O Lumbar Interbody Fusion Device (Spineology Inc.); Rampart™ T Lumbar Interbody Fusion Device (Spineology Inc.); Rampart™ A Lumbar Interbody Fusion Device (Spineology Inc.)
	K102293	Caliber® Spacer (Globus Medical Inc.)
	K113527	Opticage® Expandable Interbody Fusion Device (Interventional Spine, Inc.)

I. Purpose

The purpose of this submission is to obtain FDA clearance of the Spineology Elite™ Expandable Interbody Fusion Device which is comprised of 10mm and 12mm Elite™ Expandable implantable devices and associated surgical instrumentation.

II. Previous Submissions

510(k) #	Device Name	Purpose of 510(k)
K133459	12mm Elite™ Interbody Fusion Device	Initial Clearance
K150954	12mm Elite™ L Interbody Fusion Device	Added Device

No previous submissions have been submitted for the 10mm Elite™ Expandable device.

Spineology

510(k) Summary

III. Device Description

The Elite™ Expandable Interbody Fusion System is designed for use as a lumbar intervertebral body fusion device and consists of medical grade titanium alloy (Ti-6AL-4V, ELI) cages and implantation instrumentation. The cages are available in various geometries and sizes to accommodate patient anatomy. The cages have ridges or teeth that resist rotation and migration and have cavities to accept packing of bone graft. Components of the Elite™ IBF Expandable Lumbar Fusion System should not be used with components of any other system or manufacturer.

IV. Indications for Use

Elite™ Expandable 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.

Elite™ Expandable 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.

V. Technological Characteristics

Elite™ Expandable implants have the same technological characteristics as the predicate Elite Interbody Fusion Device, including design, intended use, material composition, and function.

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 Axial Compression
- Static and Dynamic Compression Shear
- Static Torsion

ASTM F2267
- Subsidence

Expulsion

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

VII. Conclusion

Based on the indications for use, technological characteristics, and comparison to the predicate devices, the Elite™ Expandable Interbody Fusion System has been shown to be substantially equivalent to legally marketed predicate devices.