Centinel Spine, Inc.
% Mr. Justin Eggleton
Senior Director, Spine Regulatory Affairs
Musculoskeletal Clinical Regulatory Advisers, LLC
1050 K Street NW, Suite 1000
Washington, District of Columbia 20001

May 8, 2018

Re: K173347
Trade/Device Name: STALIF C FLX™, STALIF M FLX™, STALIF L FLX™, STALIF Lateral-Oblique FLX™, ACTILIF C FLX™, ACTILIF M FLX™, ACTILIF L FLX™, and ACTILIF Lateral-Oblique FLX™
Regulation Number: 21 CFR 888.3080
Regulation Name: Intervertebral Body Fusion Device
Regulatory Class: Class II
Product Code: MAX, ODP, OVD, OVE
Dated: April 9, 2018
Received: April 9, 2018

Dear Mr. Eggleton:

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,

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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K173347

Device Name
STALIF C FLX™

Indications for Use *(Describe)*
The STALIF C FLX™ device is intended to be used as an intervertebral body fusion cage as a standalone system used with bone screws provided and requires no additional supplementary fixation systems. It is inserted between the vertebral bodies into the disc space at one or two contiguous levels from the C2/C3 disc space to the C7/T1 disc space for the treatment of cervical degenerative disc disease (defined as neck pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies). Patients with previous non-fusion spinal surgery at the treated level may be treated. The device system is designed for use with autograft bone and/or allogenic bone graft composed of cancellous and/or corticocancellous bone graft to facilitate fusion.

The cervical cage is to be used in a skeletally mature patient who has had six weeks of non-operative treatment prior to implantation of the cage.

The STALIF C FLX™ with lordotic angles greater than or equal to 10 degrees are required to be used with FDA-cleared supplemental fixation for use in the cervical 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)

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Indications for Use

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510(k) Number *(if known)*
K173347

Device Name
STALIF M FLX™

Indications for Use *(Describe)*
The STALIF M FLX™ is indicated for use with bone graft (autograft bone and/or allogenic bone graft composed of cancellous and/or corticocancellous bone graft) in patients with degenerative disc disease (DDD) at one or two contiguous levels from L2 to S1. These DDD patients may also have up to Grade I Spondylolisthesis or retrolisthesis at the involved levels. DDD is defined as discogenic back pain with degeneration of the disc confirmed by history and radiographic studies. These patients should be skeletally mature and have had six months of non-operative treatment. Patients with previous non-fusion spinal surgery at the treated level may be treated. These implants may be implanted via a laparoscopic or an open anterior approach.

The STALIF M FLX™ is a stand-alone system intended to be used with the bone screws provided and requires no additional supplementary fixation systems. The STALIF M FLX™ with lordotic angles greater than or equal to 20 degrees are required to be used with FDA-cleared supplemental fixation 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)

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510(k) Number *(if known)*
K173347

Device Name
STALIF L FLX™

Indications for Use *(Describe)*
The STALIF L FLX™ is indicated for use with bone graft (autograft bone and/or allogenic bone graft composed of cancellous and/or corticocancellous bone graft) in patients with degenerative disc disease (DDD) at one or two contiguous levels from L2 to L5. These DDD patients may also have up to Grade I spondylolisthesis or retrolisthesis at the involved levels. DDD is defined as discogenic back pain with degeneration of the disc confirmed by history and radiographic studies. These patients should be skeletally mature and have had six months of non-operative treatment. Patients with previous non-fusion spinal surgery at the treated level may be treated. These implants may be implanted via a laparoscopic or an open lateral approach. The STALIF L FLX™ is required to be used with supplementary fixation systems (e.g., pedicle screws) that have been cleared 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)

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510(k) Number *(if known)*
K173347

Device Name
STALIF Lateral-Oblique FLX™

Indications for Use *(Describe)*
The STALIF Lateral-Oblique FLX™ is indicated for use with bone graft (autograft bone and/or allogenic bone graft composed of cancellous and/or corticocancellous bone graft) in patients with degenerative disc disease (DDD) at one or two contiguous levels from L2 to L5. These DDD patients may also have up to Grade I spondylolisthesis or retrolisthesis at the involved levels. DDD is defined as discogenic back pain with degeneration of the disc confirmed by history and radiographic studies. These patients should be skeletally mature and have had six months of non-operative treatment. Patients with previous non-fusion spinal surgery at the treated level may be treated. These implants may be implanted via a laparoscopic or an open lateral approach. The STALIF Lateral-Oblique FLX™ is required to be used with supplementary fixation systems (e.g., pedicle screws) that have been cleared 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)

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See PRA Statement below.

510(k) Number *(if known)*
K173347

Device Name
ACTILIF C FLX™

Indications for Use *(Describe)*
The ACTILIF C FLX™ is intended for spinal fusion procedures at multiple contiguous levels from the C2-C3 disc to the C7-T1 disc in skeletally mature patients with degenerative disc disease (defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies) of the cervical spine. The ACTILIF C FLX™ is to be used in a patient who has had six weeks of non-operative treatment prior to implantation of the cage. Implants are intended to be packed with bone graft (autograft bone and/or allogenic bone graft composed of cancellous and/or corticocancellous bone graft). Patients with previous non- fusion spinal surgery at the treated level may be treated. The ACTILIF C FLX™ is intended to be used with a supplemental fixation system.

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)

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Indications for Use

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See PRA Statement below.

510(k) Number *(if known)*
K173347

Device Name
ACTILIF M FLX™

Indications for Use *(Describe)*
The ACTILIF M FLX™ is indicated for use with bone graft (autograft bone and/or allogenic bone graft composed of cancellous and/or corticocancellous bone graft) in patients with degenerative disc disease (DDD) at one or two contiguous levels from L2 to S1. These DDD patients may also have up to Grade I spondylolisthesis or retrolisthesis at the involved levels. DDD is defined as discogenic back pain with degeneration of the disc confirmed by history and radiographic studies. Patients with previous non-fusion spinal surgery at the treated level may be treated. These patients should be skeletally mature and have had six months of non-operative treatment. These devices are intended for intervertebral body fusion and are intended to be used with supplemental fixation instrumentation that has been 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)

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510(k) Number *(if known)*
K173347

Device Name
ACTILIF L FLX™

Indications for Use *(Describe)*
The ACTILIF L FLX™ is indicated for use with bone graft (autograft bone and/or allogenic bone graft composed of cancellous and/or corticocancellous bone graft) in patients with degenerative disc disease (DDD) at one or two contiguous levels from L2 to S1. These DDD patients may also have up to Grade I spondylolisthesis or retrolisthesis at the involved levels. DDD is defined as discogenic back pain with degeneration of the disc confirmed by history and radiographic studies. These patients should be skeletally mature and have had six months of non-operative treatment. Patients with previous non-fusion spinal surgery at the treated level may be treated. These devices are intended for intervertebral body fusion and are intended to be used with supplemental fixation instrumentation that has been cleared by the FDA for use in the lumbar spine.

Type of Use *(Select one or both, as applicable)*

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Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K173347

Device Name
ACTILIF Lateral-Oblique FLX™

Indications for Use *(Describe)*
The ACTILIF Lateral-Oblique FLX™ is indicated for use with bone graft (autograft bone and/or allogenic bone graft composed of cancellous and/or corticocancellous bone graft) in patients with degenerative disc disease (DDD) at one or two contiguous levels from L2 to S1. These DDD patients may also have up to Grade I spondylolisthesis or retrolisthesis at the involved levels. DDD is defined as discogenic back pain with degeneration of the disc confirmed by history and radiographic studies. These patients should be skeletally mature and have had six months of non-operative treatment. Patients with previous non-fusion spinal surgery at the treated level may be treated. These devices are intended for intervertebral body fusion and are intended to be used with supplemental fixation instrumentation that has been 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)

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510(k) Summary

Device Trade Name:
STALIF C FLX™
STALIF M FLX™
STALIF L FLX™ and STALIF Lateral-Oblique FLX™
ACTILIF C FLX™
ACTILIF M FLX™
ACTILIF L FLX™ and ACTILIF Lateral-Oblique FLX™

Manufacturer:
Centinel Spine, Inc.
900 Airport Road, Suite 3B
West Chester, PA 19380

Contact:
Mrs. Jessica Staub
Director, Quality and Regulatory
Centinel Spine, Inc.

Prepared by:
Mr. Justin Eggleton
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Date Prepared:
May 8, 2018

Classifications:
21 CFR §888.3080, Intervertebral body fusion device

Class:
II

Product Codes:
MAX, ODP, OVD, OVE

Primary Predicate:
The subject devices are substantially equivalent to the following primary predicate device.

Table 1: Primary Predicate Device

Manufacturer	Device Name	K Number
Centinel Spine	STALIF TT™, STALIF MIDLINE®, MIDLINE II™, MIDLINE II-Ti™	K150643

Additional Predicates: In addition to the primary predicate device, additional predicate devices cited in this 510(k) are presented in the following table.

Table 2: Additional Predicate Devices

Manufacturer	Device Name	K Number
Centinel Spine	STALIF C® and STALIF C-Ti™	K150053
Centinel Spine	STALIF X™ (STALIF L™)	K130461
EIT Spine	EIT Cellular Titanium® Cervical Cage, EIT Cellular Titanium® PLIF Cages, EIT Cellular Titanium® TLIF Cages, and EIT Cellular Titanium® ALIF Cages	K170503
Eisertech	Eisertech Cervical Cage	K122444
Eisertech	Eisertech Interbody Cage	K140348
NuVasive	CoRoent® Small Interbody System	K163491

Indications for Use and Intended Use:

STALIF C FLX™

The STALIF C FLX™ device is intended to be used as an intervertebral body fusion cage as a standalone system used with bone screws provided and requires no additional supplementary fixation systems. It is inserted between the vertebral bodies into the disc space at one or two contiguous levels from the C2/C3 disc space to the C7/T1 disc space for the treatment of cervical degenerative disc disease (defined as neck pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies). Patients with previous non-fusion spinal surgery at the treated level may be treated. The device system is designed for use with autograft bone and/or allogenic bone graft composed of cancellous and/or corticocancellous bone graft to facilitate fusion.

The cervical cage is to be used in a skeletally mature patient who has had six weeks of non-operative treatment prior to implantation of the cage.

The STALIF C FLX™ with lordotic angles greater than or equal to 10 degrees are required to be used with FDA-cleared supplemental fixation for use in the cervical spine.

STALIF M FLX™

The STALIF M FLX™ is indicated for use with bone graft (autograft bone and/or allogenic bone graft composed of cancellous and/or corticocancellous bone graft) in patients with degenerative disc disease (DDD) at one or two contiguous levels from L2 to S1. These DDD patients may also have up to Grade I Spondylolisthesis or retrolisthesis at the involved levels. DDD is defined as discogenic back pain with degeneration of the disc confirmed by history and radiographic studies. These patients should be skeletally mature and have had six months of non-operative treatment. Patients with previous non-fusion spinal surgery at the treated level may be treated. These implants may be implanted via a laparoscopic or an open anterior approach.

The STALIF M FLX™ is a stand-alone system intended to be used with the bone screws provided and requires no additional supplementary fixation systems. The STALIF M FLX™ with lordotic angles greater than or equal to 20 degrees are required to be used with FDA-cleared supplemental fixation for use in the lumbar spine.

STALIF L FLX™

The STALIF L FLX™ is indicated for use with bone graft (autograft bone and/or allogenic bone graft composed of cancellous and/or corticocancellous bone graft) in patients with degenerative disc disease (DDD) at one or two contiguous levels from L2 to L5. These DDD patients may also have up to Grade I spondylolisthesis or retrolisthesis at the involved levels. DDD is defined as discogenic back pain with degeneration of the disc confirmed by history and radiographic studies. These patients should be skeletally mature and have had six months of non-operative treatment. Patients with previous non-fusion spinal surgery at the treated level may be treated. These implants may be implanted via a laparoscopic or an open lateral approach. The STALIF L FLX™ is required to be used with supplementary fixation systems (e.g., pedicle screws) that have been cleared for use in the lumbar spine.

STALIF Lateral-Oblique FLX™

The STALIF Lateral-Oblique FLX™ is indicated for use with bone graft (autograft bone and/or allogenic bone graft composed of cancellous and/or corticocancellous bone graft) in patients with degenerative disc disease (DDD) at one or two contiguous levels from L2 to L5. These DDD patients may also have up to Grade I spondylolisthesis or retrolisthesis at the involved levels. DDD is defined as discogenic back pain with degeneration of the disc confirmed by history and radiographic studies. These patients should be skeletally mature and have had six months of non-operative treatment. Patients with previous non-fusion spinal surgery at the treated level may be treated. These implants may be implanted via a laparoscopic or an open lateral approach. The STALIF Lateral-Oblique FLX™ is required to be used with supplementary fixation systems (e.g., pedicle screws) that have been cleared for use in the lumbar spine.

ACTILIF C FLX™

The ACTILIF C FLX™ is intended for spinal fusion procedures at multiple contiguous levels from the C2-C3 disc to the C7-T1 disc in skeletally mature patients with degenerative disc disease (defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies) of the cervical spine. The ACTILIF C FLX™ is to be used in a patient who has had six weeks of non-operative treatment prior to implantation of the cage. Implants are intended to be packed with bone graft (autograft bone and/or allogenic bone graft composed of cancellous and/or corticocancellous bone graft). Patients with previous non- fusion spinal surgery at the treated level may be treated. The ACTILIF C FLX™ is intended to be used with a supplemental fixation system.

ACTILIF M FLX™

The ACTILIF M FLX™ is indicated for use with bone graft (autograft bone and/or allogenic bone graft composed of cancellous and/or corticocancellous bone graft) in patients with degenerative disc disease (DDD) at one or two contiguous levels from L2 to S1. These DDD patients may also have up to Grade I spondylolisthesis or retrolisthesis at the involved levels. DDD is defined as discogenic back pain with degeneration of the disc

confirmed by history and radiographic studies. Patients with previous non-fusion spinal surgery at the treated level may be treated. These patients should be skeletally mature and have had six months of non-operative treatment. These devices are intended for intervertebral body fusion and are intended to be used with supplemental fixation instrumentation that has been cleared by the FDA for use in the lumbar spine.

ACTILIF L FLX™

The ACTILIF L FLX™ is indicated for use with bone graft (autograft bone and/or allogenic bone graft composed of cancellous and/or corticocancellous bone graft) in patients with degenerative disc disease (DDD) at one or two contiguous levels from L2 to S1. These DDD patients may also have up to Grade I spondylolisthesis or retrolisthesis at the involved levels. DDD is defined as discogenic back pain with degeneration of the disc confirmed by history and radiographic studies. These patients should be skeletally mature and have had six months of non-operative treatment. Patients with previous non-fusion spinal surgery at the treated level may be treated. These devices are intended for intervertebral body fusion and are intended to be used with supplemental fixation instrumentation that has been cleared by the FDA for use in the lumbar spine.

ACTILIF Lateral-Oblique FLX™

The ACTILIF Lateral-Oblique FLX™ is indicated for use with bone graft (autograft bone and/or allogenic bone graft composed of cancellous and/or corticocancellous bone graft) in patients with degenerative disc disease (DDD) at one or two contiguous levels from L2 to S1. These DDD patients may also have up to Grade I spondylolisthesis or retrolisthesis at the involved levels. DDD is defined as discogenic back pain with degeneration of the disc confirmed by history and radiographic studies. These patients should be skeletally mature and have had six months of non-operative treatment. Patients with previous non-fusion spinal surgery at the treated level may be treated. These devices are intended for intervertebral body fusion and are intended to be used with supplemental fixation instrumentation that has been cleared by the FDA for use in the lumbar spine.

Device Description:

The FLX™ Platform is composed of 8 different interbody fusion implant families:

- STALIF C FLX™
- STALIF M FLX™
- STALIF L FLX™ and STALIF Lateral-Oblique FLX™
- ACTILIF C FLX™
- ACTILIF M FLX™
- ACTILIF L FLX™ and ACTILIF Lateral-Oblique FLX™

The FLX™ Platform is a novel range of interbody fusion implants with a complex randomized lattice. The Implants retain all of the benefits of the STALIF® product family while taking advantage of the benefits of porous, laser sintered Ti6Al4V. With the recent advances in additive manufacturing, titanium implants are printed with a porous scaffold structure which reduces the stiffness of the device to potentially reduce subsidence and facilitate bone growth through and around the implant.

The FLX™ Platform is intended to be implanted between the vertebral bodies into the cleared disc space to help provide stabilization and height restoration and facilitate the interbody fusion process. The device is intended to be used with bone graft (autograft bone and/or allogenic bone graft composed of cancellous and/or corticocancellous bone graft). The devices are available in a variety of heights, lengths, and widths as well as different lordotic angles to provide surgeons with a wide array of solutions for the highly variable patient population. Surgical instrumentation has been previously developed for the STALIF® Platform and is compatible with the new devices.

In addition, interbody-only versions of the FLX™ devices are available in similar size ranges as the STALIF® versions. These devices are not designed to be used with the current STALIF® ABO screw constructs and are instead to be used with supplemental fixation.

Performance Testing Summary:

The worst case devices were subjected to mechanical testing. Testing included static compression, static compression-shear, dynamic compression, dynamic compression-shear, expulsion, subsidence per ASTM F2077-14 and F2267-04. Additional analyses were performed on wear debris particles to ensure the results were consistent with predicate devices. The results demonstrate that the devices are substantially equivalent to the predicate devices.

Substantial Equivalence:

The subject devices were demonstrated to be substantially equivalent to predicates cited in the table above with respect to indications, design, materials, function, manufacturing, and performance.

Conclusion:

The Centinel Spine STALIF C FLX™, STALIF M FLX™, STALIF L FLX™, STALIF Lateral-Oblique FLX™, ACTILIF C FLX™, ACTILIF M FLX™, ACTILIF L FLX™ and ACTILIF Lateral-Oblique FLX™ are substantially equivalent to previously cleared devices with respect to its indications for use, design, function, materials, and performance.