May 4, 2018

Cutting Edge Spine, LLC
Kyle Kuntz
Manager R&D
101 Waxhaw Professional Park, Suite A
Waxhaw, North Carolina 28173

Re: K180891
Trade/Device Name: EVOL® Spinal Interbody System, EVOS Lumbar Interbody System
Regulation Number: 21 CFR 888.3080
Regulation Name: Intervertebral Body Fusion Device
Regulatory Class: Class II
Product Code: MAX
Dated: April 3, 2018
Received: April 5, 2018

Dear Kyle Kuntz:

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,

Katherine D. Kavlock -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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*

K180891

Device Name
EVOL® Spinal Interbody System

Indications for Use *(Describe)*

The EVOL® Spinal Interbody System is an intervertebral body device intended for use in skeletally mature patients with Degenerative Disc Disease (DDD) of the lumbar spine with up to Grade 1 spondylolisthesis at one or two contiguous levels from L2-S1. Degenerative disc disease is defined as discogenic back pain with degeneration of the disc confirmed by history and radiographic studies.

The EVOL® Spinal Interbody System is intended to be used with autograft and/or allograft comprised of cancellous and/or corticocancellous bone graft to facilitate fusion. It is to be used in patients who have had six months of non-operative treatment and is to be implanted via a direct posterior, transforaminal, retroperitoneal or anterior approach. The CES-PLIF and CES-LIF are implanted in pairs, while the CES-TLIF, CES-CLIF and CES-RLIF devices may be implanted singly or in pairs in the lumbosacral spine. The EVOL® Spinal Interbody System is intended to be used with supplemental fixation.

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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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)*

K180891

Device Name
EVOS Lumbar Interbody System

Indications for Use *(Describe)*

The EVOS Lumbar Interbody System is an intervertebral body device intended for use in skeletally mature patients with Degenerative Disc Disease (DDD) of the lumbar spine with up to Grade 1 spondylolisthesis at one or two contiguous levels from L2-S1. Degenerative disc disease is defined as discogenic back pain with degeneration of the disc confirmed by history and radiographic studies.

The EVOS Lumbar Interbody System is intended to be used with autograft and/or allograft comprised of cancellous and/or corticocancellous bone graft to facilitate fusion. It is to be used in patients who have had six months of non-operative treatment and is to be implanted via a direct posterior or transforaminal approach. The EVOS CURVED devices are implanted singly, while the EVOS ROTATE and EVOS STRAIGHT devices may be implanted singly or in pairs in the lumbosacral spine. The EVOS Lumbar Interbody System is intended to be used with supplemental fixation.

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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CUTTING EDGE SPINE

510(k) Summary

I. SUBMITTER

Date Prepared: 05/04/2018

Applicant:
Cutting Edge Spine, LLC
101 Waxhaw Professional Park Dr., Suite A
Waxhaw, NC 28173
Contact Person: Kyle Kuntz, Manager R&D
Tel: (704) 243-0892
e-mail: k.kuntz@cuttingedgespine.com

Application Correspondents:
Contact Person: Kyle Kuntz, Manager R&D
Tel: (704) 243-0892
e-mail: k.kuntz@cuttingedgespine.com

Alternate Contact: Shyam Patel, R&D Biomedical Engineer
Tel: (704) 243-0892
e-mail: s.patel@cuttingedgespine.com

II. DEVICE

a. EVOL® Spinal Interbody System

Trade Name:	EVOL® Spinal Interbody System
Common or Usual Name:	Intervertebral Body Fusion Device
Classification Name:	Per 21 CFR as follows: 888.3080 Intervertebral Fusion Device with Bone Graft, Lumbar
Regulatory Class:	II
Product Codes:	MAX

b. EVOS Lumbar Interbody System

Trade Name:	EVOS Lumbar Interbody System
Common or Usual Name:	Intervertebral Body Fusion Device
Classification Name:	Per 21 CFR as follows: 888.3080 Intervertebral Fusion Device with Bone Graft, Lumbar
Regulatory Class:	II
Product Codes:	MAX

III. PREDICATE DEVICES

	510(k) Number	Device	Manufacturer
Primary Predicate	**K102957**	**Cutting Edge Spine Interbody Device**	**Cutting Edge Spine**
Additional Predicate	**K150321**	**EVOS Lumbar Interbody System**	**Cutting Edge Spine**
Additional Predicate	**K170395**	**Talos® Intervertebral Body Fusion Devices**	**Meditech Spine, LLC**

IV. DEVICE DESCRIPTION

a. EVOL® Spinal Interbody System

The EVOL® Spinal Interbody System is a family of PEEK-OPTIMA or PEEK-OPTIMA HA spacers offered in a variety of widths and lengths. There are five main configurations: CES-PLIF, CES-LIF, CES-TLIF, CES-CLIF and CES-RLIF. The different configurations allow for multiple surgical technique options. The CES-PLIF, CES-LIF, CES-CLIF and CES-RLIF are generally rectangular in shape while the CES-TLIF is curved. The CES-PLIF and CES-LIF are used in pairs while the other options are used singly or in pairs.

The EVOL® Spinal Interbody System implants are available in a range of sizes, as well as parallel and lordotic angled implants, to accommodate variations in patients' anatomy. In addition, tantalum beads or pins are embedded in the spacers as an option to help allow for radiographic visualization. The hollow implants have holes through four sides for bone graft and an inserter instrument interface on the face. The implants themselves are made of biocompatible PEEK-Optima Natural (LT1) or [PEEK-Optima HA Enhanced (LT120) - CES-LIF only] polymer material (per ASTM F2026).

Teeth on top and bottom of the implants improve fixation. They are symmetrical so that the implant will resist motion equally in either direction (anterior or posterior).

b. EVOS Lumbar Interbody System

The EVOS Lumbar Interbody System is comprised of a variety of Implants manufactured from PEEK (Polyetheretherketone) -Optima LT1 and PEEK Optima LT120HA per ASTM F-2026, with Tantalum bead markers per ASTM F-560. There are three main configurations; STRAIGHT, CURVED, and ROTATE. The different configurations allow for multiple surgical technique options. The EVOS STRAIGHT and the EVOS ROTATE are generally rectangular in shape while the EVOS CURVED is curved. The

PHONE 704.243.0892
FAX 704.731.2559
101 Waxhaw Professional Park Drive, Suite A, Waxhaw, NC 28173

EVOS CURVED devices are implanted singly, while the EVOS ROTATE and EVOS STRAIGHT devices may be implanted singly or in pairs.

The EVOS device(s) are available in a range of sizes, as well as flat and biconvex endplates, and with various degrees of lordosis to accommodate variations in patients' anatomy. The angle of lordosis on each lordotic EVOS device is oriented in a way that will provide a true anterior/posterior lordotic orientation once the device has been implanted in its final intervertebral location. For example, the True Oblique Lordotic (TOL) devices have a lordotic orientation to the device that will provide a correct anterior/posterior lordotic orientation once they have been inserted at 30 degrees from the anterior/posterior midline.

Implant heights range from 6mm to 16mm in maximum height (minus the height of the teeth). Widths range from 8mm to 12mm and lengths range from 22mm to 30mm. The variety of implant shapes and sizes accommodate various surgical technique options. The hollow implants have holes through four sides for bone graft and an inserter instrument interface on the face. Teeth on top and bottom of the spacers improve fixation. The EVOS Lumbar Interbody System includes the instrumentation to facilitate the implantation of the implants.

The approach and the discectomy are conducted using standard instruments while subsequent steps are conducted using standard and/or custom instruments. The system is comprised of instruments and perforated instrument cases that are generally comprised of aluminum, stainless steel and/or polymeric materials.

The EVOS rotate and non-rotate Inserter(s) are instruments intended for use with the EVOS Lumbar Interbody System. The inserter(s) are designed specifically to implant the EVOS device into a prepared disc space. The EVOS non-rotate inserters are designed to work with the EVOS straight and curved devices while the EVOS rotate inserter is designed to work with the EVOS rotate devices.

V. INDICATIONS FOR USE

a. EVOL® Spinal Interbody System

The EVOL® Spinal Interbody System is an intervertebral body device intended for use in skeletally mature patients with Degenerative Disc Disease (DDD) of the lumbar spine with up to Grade 1 spondylolisthesis at one or two contiguous levels from L2-S1. Degenerative disc disease is defined as discogenic back pain with degeneration of the disc confirmed by history and radiographic studies.

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FAX 704.731.2559
101 Waxhaw Professional Park Drive, Suite A, Waxhaw, NC 28173

The EVOL® Spinal Interbody System is intended to be used with autograft and/or allograft comprised of cancellous and/or corticocancellous bone graft to facilitate fusion. It is to be used in patients who have had six months of non-operative treatment and is to be implanted via a direct posterior, transforaminal, retroperitoneal or anterior approach. The CES-PLIF and CES-LIF are implanted in pairs, while the CES-TLIF, CES-CLIF and CES-RLIF devices may be implanted singly or in pairs in the lumbosacral spine. The EVOL® Spinal Interbody System is intended to be used with supplemental fixation.

b. EVOS Lumbar Interbody System

The EVOS Lumbar Interbody System is an intervertebral body device intended for use in skeletally mature patients with Degenerative Disc Disease (DDD) of the lumbar spine with up to Grade 1 spondylolisthesis at one or two contiguous levels from L2-S1. Degenerative disc disease is defined as discogenic back pain with degeneration of the disc confirmed by history and radiographic studies.

The EVOS Lumbar Interbody System is intended to be used with autograft and/or allograft comprised of cancellous and/or corticocancellous bone graft to facilitate fusion. It is to be used in patients who have had six months of non-operative treatment and is to be implanted via a direct posterior or transforaminal approach. The EVOS CURVED devices are implanted singly, while the EVOS ROTATE and EVOS STRAIGHT devices may be implanted singly or in pairs in the lumbosacral spine. The EVOS Lumbar Interbody System is intended to be used with supplemental fixation.

VI. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH PREDICATE DEVICES

Documentation was submitted which demonstrated that the EVOL® Spinal Interbody System and the EVOS Lumbar Interbody System are substantially equivalent to the predicate devices based on a comparison of the following characteristics:

- FDA product codes
- Indications for Use
- Anatomical Region
- Implant Materials
- Product Dimensions
- Device Features
- Mechancial Performance
- Available by prescription only
- Made for single use

PHONE 704.243.0892
FAX 704.731.2559
101 Waxhaw Professional Park Drive, Suite A, Waxhaw, NC 28173

CUTTING EDGE SPINE

VII. NON-CLINICAL AND CLINICAL PERFORMANCE TESTING

a. EVOL® Spinal Interbody System

Static Compression, Static Compression Shear and Dynamic Compression testing was performed per ASTM F2026. Expulsion testing was also performed. Testing performed showed substantial equivalence to the predicate.

b. EVOS Lumbar Interbody System

No design changes were made to the existing devices, nor were any new components added to the system. Therefore, no additional testing was required or performed.

VIII. CONCLUSIONS

a. EVOL® Spinal Interbody System

Based upon a comparison of technological characteristics, intended use, design features, and mechanical performance, the addition of EVOL® Spinal Interbody System spacers (CES-LIF spacers only) made from LT120 does not raise any new safety or efficacy concerns nor does the addition of allograft comprised of cancellous and/or corticocancellous bone graft to the indications. The data presented in this submission demonstrates that the devices listed above are substantially equivalent to the predicate devices.

b. EVOS Lumbar Interbody System

No design changes were made to the existing devices, nor were any new components added to the system. The indications were expanded to include the use of allograft comprised of cancellous and/or corticocancellous bone graft like the predicate. The data presented in this submission demonstrates that the devices listed above are substantially equivalent to the predicate devices.

PHONE 704.243.0892
FAX 704.731.2559
101 Waxhaw Professional Park Drive, Suite A, Waxhaw, NC 28173