May 13, 2020

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

Re: K200991
Trade/Device Name: EVOL® Spinal Interbody System
Regulation Number: 21 CFR 888.3080
Regulation Name: Intervertebral Body Fusion Device
Regulatory Class: Class II
Product Code: MAX
Dated: April 13, 2020
Received: April 15, 2020

Dear Mr. 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. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. 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) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; 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 https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). 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 (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Brent Showalter, Ph.D.
Assistant Director (Acting)
DHT6B: Division of Spinal Devices
OHT6: Office of Orthopedic Devices
Office of Product Evaluation and Quality
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)*

K200991

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 or anterior approach. The CES-LIF is implanted 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.

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CUTTING EDGE SPINE

510(k) Summary

I. SUBMITTER

Date Prepared: 05/13/2020

Applicant:
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Tel: (704) 243-0892
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II. DEVICE

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

CUTTING EDGE SPINE

III. PREDICATE DEVICES

	510(k) Number	Device	Manufacturer
Primary Predicate	**K102957**	**Cutting Edge Spine Interbody Device**	**Cutting Edge Spine**
Additional Predicate	**K180891**	**EVOL® Spinal Interbody System (formerly Cutting Edge Spine Interbody Device)**	**Cutting Edge Spine**
Additional Predicate	**K192497**	**EVOL® ha - D Lateral Interbody Fusion System**	**Cutting Edge Spine**

IV. DEVICE DESCRIPTION

The EVOL® Spinal Interbody System is a family of PEEK-OPTIMA® HA Enhanced spacers offered in a variety of widths and lengths. The CES-LIF are generally rectangular in shape. The CES-LIF is used in pairs.

The EVOL® Spinal Interbody System implants are available in a range of sizes to accommodate variations in patients' anatomy. In addition, tantalum beads are embedded in the spacers 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 CES-LIF HA implants themselves are made of biocompatible PEEK-Optima® HA Enhanced (LT120) polymer material and provided non-sterile for single-use.

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).

The purpose of this submission is to add a new sterilization method.

V. INDICATIONS FOR USE

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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CUTTING EDGE SPINE

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 or anterior approach. The CES-LIF is implanted in pairs in the lumbosacral spine. The EVOL® Spinal 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 is 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
- Sterilization Method

VII. NON-CLINICAL AND CLINICAL PERFORMANCE TESTING

No additional testing is required to determine if Steam as a sterilization method will impact the safety or efficacy of this implant.

VIII. CONCLUSIONS

Based upon a comparison of technological characteristics, intended use, design features, and mechanical performance, the addition of steam sterilization to EVOL® Spinal Interbody System spacers does not raise any new concerns of safety or efficacy. The data presented in this submission demonstrates that the devices listed above are substantially equivalent to the predicate devices.

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