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

June 25, 2018

Re: K180674
Trade/Device Name: EVOL® ha-C Cervical Interbody Fusion System
Regulation Number: 21 CFR 888.3080
Regulation Name: Intervertebral Body Fusion Device
Regulatory Class: Class II
Product Code: ODP
Dated: June 13, 2018
Received: June 13, 2018

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. 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 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,

Melissa Hall -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)*

K180674

Device Name
EVOL® ha – C Cervical Interbody Fusion System

Indications for Use *(Describe)*

The EVOL® ha – C Cervical Interbody Fusion System is intended for intervertebral body fusion of the spine in skeletally mature patients. The EVOL® ha – C Cervical Interbody Fusion System is indicated for use for anterior cervical interbody fusion in patients with degenerative disc disease (DDD) at up to two contiguous levels from C2 - T1. DDD is defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies. The EVOL® ha – C Cervical Interbody Fusion System is intended to be used with supplemental fixation. The EVOL® ha – C Cervical Interbody Fusion System is intended for use with autogenous and/or allogeneic bone graft comprised of cancellous, and/or corticocancellous bone graft to facilitate fusion. The cervical devices are to be used in patients who have had at least six weeks of non-operative treatment.

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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510(k) Summary

I. SUBMITTER

Date Prepared: 03/05/2018

Applicant:
Cutting Edge Spine, LLC
101 Waxhaw Professional Park Dr., Suite A
Waxhaw, NC 28173
Contact Person: Kyle Kuntz, Manager R&D
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Tel: (704) 243-0892
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II. DEVICE

Trade Name:	EVOL® ha – C Cervical Interbody Fusion System
Common or Usual Name:	Intervertebral Body Fusion Device
Classification Name:	Per 21 CFR as follows: 888.3080 Intervertebral Fusion Device with Bone Graft, Cervical
Regulatory Class:	II
Product Codes:	ODP

III. PREDICATE DEVICES

	510(k) Number	Device	Manufacturer
Primary Predicate	**K150362**	**CoRoent Small Interbody System**	**Nuvasive**
Additional Predicate	**K142026**	**Arena-C (HA)**	**Spine Frontier**
Additional Predicate	**K081730**	**Novel Spacer System**	**Alphatec Spine**
Additional Predicate	**K150321**	**EVOS Lumbar Interbody System**	**Cutting Edge Spine**

IV. DEVICE DESCRIPTION

The purpose of this application is to introduce a new medical device in commercial distribution (marketing). The EVOL® ha – C Cervical Interbody Fusion System is designed for use as a cervical interbody fusion device and consists of various sizes to accommodate individual patient anatomy. The sizes vary by footprint (width and depth), height, and lordotic angle. All sizes have a central window for autogenous and/or allogeneic bone graft comprised of cancellous, and/or corticocancellous bone graft. The inferior and superior faces have teeth to resist migration when placed in between the vertebral bodies. Each spacer has tantalum beads, per ASTM F560, imbedded in the device to aid visualization under fluoroscopy. The implants are manufactured from PEEK-OPTIMA® LT120 HA (Invibio) per ASTM F2026.

V. INDICATIONS FOR USE

The EVOL® ha – C Cervical Interbody Fusion System is intended for intervertebral body fusion of the spine in skeletally mature patients. The EVOL® ha – C Cervical Interbody Fusion System is indicated for use for anterior cervical interbody fusion in patients with degenerative disc disease (DDD) at up to two contiguous levels from C2 - T1. DDD is defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies. The EVOL® ha – C Cervical Interbody Fusion System is intended to be used with supplemental fixation. The EVOL® ha – C Cervical Interbody Fusion System is intended for use with autogenous and/or allogeneic bone graft comprised of cancellous, and/or corticocancellous bone graft to facilitate fusion. The cervical devices are to be used in patients who have had at least six weeks of non-operative treatment.

VI. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH PREDICATE DEVICES

Documentation was submitted which demonstrated that the EVOL® ha – C Cervical Interbody Fusion System is substantially equivalent to the predicate devices based on a comparison of the following characteristics:

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

VII. NON-CLINICAL AND CLINICAL PERFORMANCE TESTING

Testing was performed for the EVOL® ha – C Cervical Interbody Fusion System and demonstrated substantial equivalent performance to the identified predicates. The mechanical tests were performed in accordance to these test methods:

- ASTM F2077
- ASTM F2267
- Expulsion Testing

The tests performed include: static & dynamic tests for compression, torsion, and compression shear. Subsidence and expulsion tests were also performed.

Comprehensive, clinical literature review of published data for cervical interbody fusion devices, similar to the EVOL® ha – C Cervical Interbody Fusion System, was performed to support the Indications for Use at two levels. Based on the published clinical literature review, it was determined that the cervical interbody fusion device, similar to the EVOL® ha – C Cervical Interbody Fusion System, used in the treatment of two-level cervical degenerative disc disease has a safety and effectiveness profile that is similar to the predicate device.

In all, the biomechanical testing results demonstrate the EVOL® ha – C Cervical Interbody Fusion System is substantially equivalent to the predicate devices.

VIII. CONCLUSIONS

Based upon a comparison of technological characteristics, intended use, design features, and mechanical performance, the EVOL® ha – C Cervical Interbody Fusion System has demonstrated substantial equivalence to the identified predicates.