January 6, 2020

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

Re: K192497
Trade/Device Name: EVOL® ha - D Lateral Interbody Fusion System
Regulation Number: 21 CFR 888.3080
Regulation Name: Intervertebral Body Fusion Device
Regulatory Class: Class II
Product Code: MAX
Dated: December 10, 2019
Received: December 11, 2019

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 L. Showalter
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)*

K192497

Device Name
EVOL® ha – D Lateral Interbody Fusion System

Indications for Use *(Describe)*

The EVOL® ha – D Lateral Interbody Fusion System is intended for intervertebral body fusion of the spine in skeletally mature patients. EVOL® ha – D Lateral Interbody Fusion System is indicated for use at either one level or two contiguous levels in the lumbar spine (L2-S1) for the treatment of degenerative disc disease (DDD) with up to Grade I spondylolisthesis. DDD is defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies. The EVOL® ha – D Lateral Interbody Fusion System is designed for use with autogenous and/or allogeneic bone graft comprised of cancellous and/or corticocancellous bone graft to facilitate fusion and supplemental fixation system cleared by the FDA for use in the lumbosacral spine. The devices are to be used in patients who have had at least six months 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.**

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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# 6. 510(k) Summary

## I. SUBMITTER

**Date Prepared: 9/6/2019**

Applicant:
Cutting Edge Spine, LLC
101 Waxhaw Professional Park Dr., Suite A
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Tel: (704) 243-0892
e-mail: s.patel@cuttingedgespine.com

## II. DEVICE

| | |
|---|---|
| Trade Name: | EVOL® ha – D Lateral Interbody Fusion System |
| Common or Usual Name: | Intervertebral Body Fusion Device |
| Classification Name: | Per 21 CFR as follows:<br>888.3080<br>Intervertebral Fusion Device with Bone Graft, Lumbar |
| Regulatory Class: | II |
| Product Codes: | MAX |

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## III. PREDICATE DEVICES

| | 510(k) Number | Device | Manufacturer |
|---|---|---|---|
| Primary Predicate | K153782 | Lumbar Interbody Implants | NuVasive |
| Additional Predicate | K180674 | EVOL® ha – C Cervical Interbody Fusion System | Cutting Edge Spine |
| Additional Predicate | K102957 | Spinal Interbody Device (EVOL) | Cutting Edge Spine |

## IV. DEVICE DESCRIPTION

The purpose of this submission to request approval for a new product. The EVOL® ha – D Lateral Interbody Fusion System is designed for use as a lumbar 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 two central windows for 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 – D Lateral Interbody Fusion System is intended for intervertebral body fusion of the spine in skeletally mature patients. EVOL® ha – D Lateral Interbody Fusion System is indicated for use at either one level or two contiguous levels in the lumbar spine (L2-S1) for the treatment of degenerative disc disease (DDD) with up to Grade I spondylolisthesis. DDD is defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies. The EVOL® ha – D Lateral Interbody Fusion System is designed for use with autogenous and/or allogeneic bone graft comprised of cancellous and/or corticocancellous bone graft to facilitate fusion and supplemental fixation system cleared by the FDA for use in the lumbosacral spine. The devices are to be used in patients who have had at least six months of non-operative treatment.

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## VI. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH PREDICATE DEVICES

Documentation was submitted which demonstrated that the EVOL® ha – D Lateral 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 – D Lateral Interbody Fusion System and demonstrated substantial equivalent performance to the identified predicate. 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, and compression shear. Subsidence and expulsion tests were also performed.

In all, the biomechanical testing results demonstrate the EVOL® ha – D Lateral Interbody Fusion System is substantially equivalent to the predicate device.

## VIII. CONCLUSIONS

Based upon a comparison of technological characteristics, intended use, design features, and mechanical performance, the EVOL® ha – D Lateral Interbody Fusion System does not raise any new safety or efficacy concerns and has demonstrated substantial equivalence to the identified predicates.