March 12, 2025

Cutting Edge Spine, LLC
Kyle Kuntz
Manager R&D
6012 Waxhaw Hwy
Mineral Springs, North Carolina 28108

Re: K250605
Trade/Device Name: EVOL® ha - Hyper 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: February 28, 2025
Received: February 28, 2025

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device"

(https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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 -S

Brent Showalter, Ph.D.
Assistant Director
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: 07/31/2026
See PRA Statement below.

Submission Number *(if known)*

K250605

Device Name

EVOL® ha – Hyper C Cervical Interbody Fusion System

Indications for Use *(Describe)*

The EVOL® ha – Hyper C Cervical Interbody Fusion System is intended for intervertebral body fusion of the spine in skeletally mature patients. The EVOL® ha – Hyper C Cervical Interbody Fusion System is indicated for use for anterior cervical interbody fusion in patients with cervical disc disease, instability, trauma including fractures, deformity defined as kyphosis, lordosis, or scoliosis, cervical spondylotic myelopathy, spinal stenosis, and failed previous fusion. Cervical disc disease is defined as intractable radiculopathy and/or myelopathy with herniated disc and/or osteophyte formation on posterior vertebral endplates producing symptomatic nerve root and/or spinal cord compression confirmed by radiographic studies at up to two contiguous levels from C2 - T1.

The EVOL® ha – Hyper C Cervical Interbody Fusion System is intended to be used with supplemental fixation. The EVOL® ha – Hyper C Cervical Interbody Fusion System is intended for use with autogenous and/or allogeneic bone graft comprised of cancellous, cortical, 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.

510(k) #: K250605

510(k) Summary

Prepared on: 2025-02-28

Contact Details

21 CFR 807.92(a)(1)

Applicant Name	Cutting Edge Spine, LLC
Applicant Address	6012 Waxhaw Hwy Mineral Springs NC 28108 United States
Applicant Contact Telephone	704-243-0982x2
Applicant Contact	Mr. Kyle Kuntz
Applicant Contact Email	k.kuntz@cuttingedgespine.com

Device Name

21 CFR 807.92(a)(2)

Device Trade Name	EVOL® ha – Hyper C Cervical Interbody Fusion System
Common Name	Intervertebral body fusion device
Classification Name	Intervertebral Fusion Device With Bone Graft, Cervical
Regulation Number	888.3080
Product Code(s)	ODP

Legally Marketed Predicate Devices

21 CFR 807.92(a)(3)

Predicate #	Predicate Trade Name (Primary Predicate is listed first)	Product Code
K180674	EVOL® ha – C Cervical Interbody Fusion System	ODP
K182284	Tyber Medical PT Interbody Spacer	ODP

Device Description Summary

21 CFR 807.92(a)(4)

The EVOL® ha – Hyper 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 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.

Intended Use/Indications for Use

21 CFR 807.92(a)(5)

The EVOL® ha – Hyper C Cervical Interbody Fusion System is intended for intervertebral body fusion of the spine in skeletally mature patients. The EVOL® ha – Hyper C Cervical Interbody Fusion System is indicated for use for anterior cervical interbody fusion in patients with cervical disc disease, instability, trauma including fractures, deformity defined as kyphosis, lordosis, or scoliosis, cervical spondylotic myelopathy, spinal stenosis, and failed previous fusion. Cervical disc disease is defined as intractable radiculopathy and/or myelopathy with herniated disc and/or osteophyte formation on posterior vertebral endplates producing symptomatic nerve root and/or spinal cord compression confirmed by radiographic studies at up to two contiguous levels from C2 - T1.

The EVOL® ha – Hyper C Cervical Interbody Fusion System is intended to be used with supplemental fixation. The EVOL® ha – Hyper C Cervical Interbody Fusion System is intended for use with autogenous and/or allogeneic bone graft comprised of cancellous, cortical, 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.

Indications for Use Comparison 21 CFR 807.92(a)(5)

While the intended use remains unchanged, the Indications for Use has been reworded to use language from both predicates.

Technological Comparison 21 CFR 807.92(a)(6)

The subject device is substantially equivalent to the predicates EVOL® ha – C Cervical Interbody Fusion System (K180674) and Tyber Medical PT Interbody Spacer (K182284). The subject device is intended for intervertebral body fusion of the spine in skeletally mature patients.

Cutting Edge Spine, LLC, has demonstrated that, per FDA's regulation of medical devices 888.3040, the subject device is substantially equivalent to the predicate devices based on a comparison of the following characteristics:

- FDA product code
- Indications for use
- Surgical Approach
- Anatomical Region
- Implant Materials
- Product Dimensions
- Mechanical Performance
- Available by prescription only
- Made for single use
- Sterility Assurance Level (SAL)
- Technology

The EVOL® ha – Hyper C Cervical Interbody Fusion System and the predicate devices share similarities in intended use, technology, materials, operating principles, design, device features, and performance. These combined predicate characteristics include being manufactured from PEEK per ASTM F2026 with tantalum markers per ASTM F560, being offered in various footprint sizes and heights, having central windows for bone graft, teeth to resist motion and having various lordodic angles.

The differences in technological characteristics between the EVOL® ha – Hyper C Cervical Interbody Fusion System and the predicate devices are the sizes offered. The subject EVOL® ha – Hyper C Cervical Interbody Fusion System offers sizes that are potentially a new worst case for Cutting Edge Spine for some of the required mechanical testing when compared to the predicate EVOL® ha – C Cervical Interbody Fusion System (K180674). These differences are implemented without limiting strength or structural integrity.

The scientific methods used are acceptable and can satisfactorily evaluate the difference in technological characteristics which do not raise additional questions about safety and effectiveness compared to the predicate devices. Therefore, it can be concluded that the EVOL® ha – Hyper C Cervical Interbody Fusion System is both safe and effective and demonstrates substantial equivalence to the predicate.

Non-Clinical and/or Clinical Tests Summary & Conclusions 21 CFR 807.92(b)

Additional testing was performed to determine that a change to the product offering (sizes) will not impact the safety or efficacy of this implant. The testing performed included ASTM F2077 and expulsion testing. A summary of the test data is included.

Based upon a comparison of technological characteristics, intended use, design features, and mechanical performance, EVOL® ha – Hyper C Cervical Interbody Fusion System 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.