August 12, 2024

Evolution Spine
Todd Wallenstein
VP R&D, Quality, Regulatory
2300 N. Haskell Ave
Dallas, Texas 75204

Re: K241846
Trade/Device Name: E3D™-C Interbody System
Regulation Number: 21 CFR 888.3080
Regulation Name: Intervertebral Body Fusion Device
Regulatory Class: Class II
Product Code: ODP, OVE
Dated: June 17, 2024
Received: June 26, 2024

Dear Todd Wallenstein:

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.

FDA's substantial equivalence determination also included the review and clearance of your Predetermined Change Control Plan (PCCP). Under section 515C(b)(1) of the Act, a new premarket notification is not required for a change to a device cleared under section 510(k) of the Act, if such change is consistent with an

established PCCP granted pursuant to section 515C(b)(2) of the Act. Under 21 CFR 807.81(a)(3), a new premarket notification is required if there is a major change or modification in the intended use of a device, or if there is a change or modification in a device that could significantly affect the safety or effectiveness of the device, e.g., a significant change or modification in design, material, chemical composition, energy source, or manufacturing process. Accordingly, if deviations from the established PCCP result in a major change or modification in the intended use of the device, or result in a change or modification in the device that could significantly affect the safety or effectiveness of the device, then a new premarket notification would be required consistent with section 515C(b)(1) of the Act and 21 CFR 807.81(a)(3). Failure to submit such a premarket submission would constitute adulteration and misbranding under sections 501(f)(1)(B) and 502(o) of the Act, respectively.

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.

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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K241846

Device Name
E3D™-C Interbody System

Indications for Use *(Describe)*

E3D™-C Interbody System includes interbody fusion devices indicated at one or more levels of the cervical spine (C2-T1) in patients with cervical degenerative disc disease (DDD), 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. These patients should be skeletally mature and have had at least six (6) weeks of non-operative treatment. These devices are to be filled with autograft bone and/or allogenic bone graft composed of cancellous, cortical, and/or corticocancellous bone.

E3D™-C Static Interbodies are intended to be used with supplemental fixation (e.g. cervical plates or cervical posterior fixation).

E3D™-C Integrated Interbodies are intended to be used with screws or anchors. When used with two screws, these devices are stand-alone interbody fusion devices. When used with anchors, or without screws, these devices are intended to be used with supplemental fixation (e.g. cervical plates or cervical posterior 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.

510(k) Summary

In accordance with Title 21 of the Code of Federal Regulations, Part 807, and in particular 21 CFR §807.92, the following summary of information is provided:

Company: Evolution Spine
2300 N Haskell Rd
Dallas, TX 75204

Contact: Todd Wallenstein
Evolution Spine
2300 N Haskell Ave
Dallas, TX 75204
Phone: 571-594-7409
twallenstein@evolutionspine.com

Date Prepared: June 20, 2024

Device Trade Name: E3D™-C Interbody System
Common Name: Intervertebral Body Fusion Device
Classification: 21 CFR §888.3080
Class: II
Product Code: ODP, OVE

Primary Predicate: **Globus HEDRON™ Cervical Spacers (K222270)**
Additional Predicates: **Globus COALITION™ Cervical Spacers (K151939)**
DIOMEDICAL AEON-C™ Stand Alone System (K191477)
Evolution Spine Interbody System (K223146, K232432, & K240368)

Device Description:

The E3D™-C Interbody System provides interbody fusion devices designed to provide structural stability during spinal fusion. The E3D™-C Interbody System consists of Interbodies offered in various sizes to accommodate surgical needs and anatomic requirements. The E3D™-C Interbodies were designed to be placed via an anterior approach. All Interbodies in the system are additively manufactured from titanium alloy powder, per ASTM F3001. The System offers both Static and Integrated Interbodies. The Integrated version is to be used in conjunction with two (2) screws that are subtractively manufactured from titanium alloy, per ASTM F136 or two (2) anchors that are additively manufactured from titanium alloy powder, per ASTM F3001.

Integrated Interbodies were designed to accept two bone screws or anchors which are used to fixate into the adjacent vertebral bodies. When appropriate, the Integrated Interbodies may be used as a stand-alone system when used with screws. The Titanium Alloy (Ti-6Al-4V ELI) Interbodies are manufactured using an additive Direct Metal Laser Sintering (DMLS) 3D-printing process which enables the creation of the system's double lattice architecture. The double lattice architecture was designed to encourage bone growth on and through the cage. The Integrated Interbody has two screw holes as well as an integral cam locking mechanism to prevent screw back-out.

The E3D™-C Interbody System's implants are available with and without HA^{nano} Surface®, a 20-40 nanometer thin hydroxyapatite (HA) surface treatment. The surface treatment presents nano-scale topography on the entirety of the implant surface.

Indications For Use:
E3D™-C Interbody System includes interbody fusion devices indicated at one or more levels of the cervical spine (C2-T1) in patients with cervical degenerative disc disease (DDD), 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. These patients should be skeletally mature and have had at least six (6) weeks of non-operative treatment. These devices are to be filled with autograft bone and/or allogenic bone graft composed of cancellous, cortical, and/or corticocancellous bone.

E3D™-C Static Interbodies are intended to be used with supplemental fixation (e.g. cervical plates or cervical posterior fixation).

E3D™-C Integrated Interbodies are intended to be used with screws or anchors. When used with two screws, these devices are stand-alone interbody fusion devices. When used with anchors, or without screws, these devices are intended to be used with supplemental fixation (e.g. cervical plates or cervical posterior fixation).

Substantial Equivalence:
The subject E3D™-C Interbody System has been demonstrated to be substantially equivalent with respect to indications, design, materials, function, manufacturing, and/or performance as compared to the predicate devices.

Performance Data:
Testing on the E3D™-C Interbody System included static compression, static shear, static torsion, dynamic compression, dynamic shear, and dynamic torsion per ASTM F2077. Additional testing included wear debris analysis per ASTM F1877, expulsion, and subsidence per ASTM F2267. The results demonstrate that the E3D™-C Interbody System is substantially equivalent to predicate devices.

Conclusion:
Based on the indications for use, technological characteristics, performance testing, and comparison to predicate devices, the subject E3D™-C Interbody System has been shown to be substantially equivalent to legally marketed predicate devices.