February 4, 2026

Evolution Spine
Quynh Tran
Associate Product Development Engineer
2300 N. Haskell Ave.
Dallas, Texas 75204

Re: K260038
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: January 5, 2026
Received: January 6, 2026

Dear Quynh Tran:

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 Management System Regulation (QMSR) (21 CFR Part 820), which includes, but is not limited to, ISO 13485 clause 7.3 (Design controls), ISO 13484 clause 8.3 (Nonconforming product), and ISO 13485 clause 8.5 (Corrective and preventative action). Please note that regardless of whether a change requires premarket review, the QMSR requires device manufacturers to review and approve changes to device design and production (ISO 13485 clause 7.3 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 Management System Regulation (QMSR) (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,

KATHERINE D.
KAVLOCK -S

for
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

Indications for Use

Please type in the marketing application/submission number, if it is known. This textbox will be left blank for original applications/submissions.	K260038

Please provide the device trade name(s).

E3D™-C Interbody System

Please provide your Indications for Use below.

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).

Please select the types of uses (select one or both, as applicable).

- ☒ Prescription Use (21 CFR 801 Subpart D)
- ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

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: Quynh Tran
Evolution Spine
2300 N Haskell Ave
Dallas, TX 75204
Phone: 469-486-3305
qtran@evolutionspine.com

Date Prepared: January 5, 2026

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: **E3D-C™ Interbody System (K241846)**
Additional Predicate: **Alphatec Spine IdentiTi™ NanoTec™ Interbody System (K211805)**

Purpose of Submission:
The purpose of this submission is to gain clearance for adding additional implant footprints in 20x14mm, 20x16mm, & 22x19mm size to the Evolution Spine E3D-C™ Interbody System. The Evolution Spine E3D-C™ Interbody System device has been previously submitted and cleared under 510(k) K241846.

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.

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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 implants proposed in this submission are identical to the predicate device (K241846) in principle of operation, indications for use, stabilization method, anatomic location and approach, product code and classification, sterilization process, material, and biocompatibility. The additional footprints are within the size range of the additional predicate, Alphatec Spine IdentiTi™ NanoTec™ Interbody System (K211805). The subject E3D™-C Interbody System has been shown to be substantially equivalent to legally marketed predicate devices.

Performance Data:
Mechanical testing performed on the predicate (K241846) applies to the subject devices because the subject devices did not introduce a new worst-case geometry. Testing of the original 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. Predicate testing remains applicable, and the new subject devices' performance is equivalent to the primary predicate (K241846).

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