February 7, 2023

Evolution Spine
Mr. Todd Wallenstein
VP Regulatory/Quality
2300 N. Haskell Ave
Dallas, Texas 75204

Re: K223146
Trade/Device Name: EVOLUTION SPINE Interbody System
Regulation Number: 21 CFR 888.3080
Regulation Name: Intervertebral Body Fusion Device
Regulatory Class: Class II
Product Code: OVD, MAX, PHM
Dated: December 15, 2022
Received: December 16, 2022

Dear Mr. 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 (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 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)*
K223146

Device Name
Evolution Spine Interbody System

Indications for Use *(Describe)*
Evolution Spine Static Interbody Devices are thoraco-lumbar interbody fusion devices indicated at one or more levels of the thoracic spine (T1-T12), thoracolumbar junction (T12- L1), or lumbosacral spine (L1-S1) as an adjunct to fusion in patients with the following indications: degenerative disc disease (DDD), disc herniation (with myelopathy and/or radiculopathy), spondylolisthesis, deformity (degenerative scoliosis or kyphosis), spinal stenosis, and failed previous fusion (pseudarthrosis). DDD is defined as discogenic back pain with degeneration of the disc as confirmed by history and radiographic studies. These patients should be skeletally mature and have had at least six (6) months of non-operative treatment. Devices are to be filled with autograft bone and/or allogenic bone graft composed of cancellous and/or corticocancellous bone. These devices are intended to be used with supplemental fixation systems that have been cleared for use in the thoracolumbosacral spine (e.g., posterior pedicle screw and rod systems, anterior plate systems, and anterior screw and rod systems). Hyperlordotic interbody devices (≥20° lordosis) must be used with at least anterior supplemental fixation.

Evolution Spine Integrated Interbody Devices are integrated lumbar interbody fusion devices intended for use in patients with degenerative disc disease (DDD) at one or two contiguous levels of the lumbosacral spine (L2-S1). DDD is defined as discogenic back pain with degeneration of the disc confirmed by history and radiographic studies. These patients should be skeletally mature and have had at least six (6) months of non-operative treatment. In addition, these patients may have up to Grade 1 spondylolisthesis or retrolisthesis at the involved level(s). Devices are to be filled with autograft bone and/or allogenic bone graft composed of cancellous and/or corticocancellous bone. These devices are intended to be used with three screws or anchors which accompany the implants. When used with screws, these devices are stand-alone interbody fusion devices. When used with anchors, these devices are intended for use with supplemental fixation (e.g. facet screws or posterior fixation). Hyperlordotic implants (≥25° lordosis) are intended for use with supplemental fixation (e.g. facet screws or posterior fixation). When used without screws or anchors, these devices are intended for use with supplemental fixation (e.g. facet screws or posterior fixation).

When used for multilevel degenerative scoliosis or sagittal deformity, supplemental fixation that have been cleared for use in the thoracolumbosacral spine (e.g., posterior pedicle screw and rod systems, anterior plate systems, and anterior screw and rod systems) must be used.

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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510(k) Summary - K223146

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: February 1, 2023

Device Trade Name: EVOLUTION SPINE Interbody System
Common Name: Intervertebral Body Fusion Device
Classification: 21 CFR §888.3080
Class: II
Product Code: OVD, MAX, PHM

Primary Predicate: **Globus HEDRON Lumbar Spacers (K191391)**
Additional Predicates: **Genesys Spine Apache® Interbody Fusion System (K103034)**
Reference Devices: **PISCES-SA Standalone ALIF Interbody System (K213935)**
TransLoc 3D (K211496)

Device Description:
The EVOLUTION SPINE Interbody System provides interbody fusion devices designed to provide structural stability during spinal fusion. The EVOLUTION SPINE Interbody System consists of interbodies offered in various sizes to accommodate surgical needs and anatomic requirements. The EVOLUTION SPINE 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 three (3) screws that are subtractively manufactured from titanium alloy, per ASTM F136.

Indications For Use:
Evolution Spine Static Interbody Devices are thoraco-lumbar interbody fusion devices indicated at one or more levels of the thoracic spine (T1-T12), thoracolumbar junction (T12- L1), or lumbosacral spine (L1-S1) as an adjunct to fusion in patients with the following indications: degenerative disc disease (DDD), disc herniation (with myelopathy and/or radiculopathy), spondylolisthesis, deformity

(degenerative scoliosis or kyphosis), spinal stenosis, and failed previous fusion (pseudarthrosis). DDD is defined as discogenic back pain with degeneration of the disc as confirmed by history and radiographic studies. These patients should be skeletally mature and have had at least six (6) months of non-operative treatment. Devices are to be filled with autograft bone and/or allogenic bone graft composed of cancellous and/or corticocancellous bone. These devices are intended to be used with supplemental fixation systems that have been cleared for use in the thoracolumbosacral spine (e.g., posterior pedicle screw and rod systems, anterior plate systems, and anterior screw and rod systems). Hyperlordotic interbody devices (≥20° lordosis) must be used with at least anterior supplemental fixation.

Evolution Spine Integrated Interbody Devices are integrated lumbar interbody fusion devices intended for use in patients with degenerative disc disease (DDD) at one or two contiguous levels of the lumbosacral spine (L2-S1). DDD is defined as discogenic back pain with degeneration of the disc confirmed by history and radiographic studies. These patients should be skeletally mature and have had at least six (6) months of non-operative treatment. In addition, these patients may have up to Grade 1 spondylolisthesis or retrolisthesis at the involved level(s). Devices are to be filled with autograft bone and/or allogenic bone graft composed of cancellous and/or corticocancellous bone. These devices are intended to be used with three screws or anchors which accompany the implants. When used with screws, these devices are stand-alone interbody fusion devices. When used with anchors, these devices are intended for use with supplemental fixation (e.g. facet screws or posterior fixation). Hyperlordotic implants (≥25° lordosis) are intended for use with supplemental fixation (e.g. facet screws or posterior fixation). When used without screws or anchors, these devices are intended for use with supplemental fixation (e.g. facet screws or posterior fixation).

When used for multilevel degenerative scoliosis or sagittal deformity, supplemental fixation that have been cleared for use in the thoracolumbosacral spine (e.g., posterior pedicle screw and rod systems, anterior plate systems, and anterior screw and rod systems) must be used.

Substantial Equivalence:
The subject EVOLUTION SPINE 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 EVOLUTION SPINE Interbody System included static compression, static shear, dynamic compression, and dynamic shear per ASTM F2077. Additional testing included wear debris analysis per ASTM F1877, expulsion, and subsidence per ASTM F2267. The results demonstrate that the EVOLUTION SPINE 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 EVOLUTION SPINE Interbody System has been shown to be substantially equivalent to legally marketed predicate devices.