June 18, 2025

Curiteva, Inc.
Eric Linder
Chief Technology Officer
25127 Will McComb Drive
Tanner, Alabama 35671

Re: K250845
Trade/Device Name: Curiteva Porous PEEK Standalone ALIF System
Regulation Number: 21 CFR 888.3080
Regulation Name: Intervertebral Body Fusion Device
Regulatory Class: Class II
Product Code: OVD, MAX, PHM
Dated: March 20, 2025
Received: March 20, 2025

Dear Mr. Linder:

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

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.	K250845

Please provide the device trade name(s).

Curiteva Porous PEEK Standalone ALIF System

Please provide your Indications for Use below.

Curiteva Porous PEEK Standalone ALIF System

The Curiteva Porous PEEK Standalone ALIF devices are 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 I spondylolisthesis or retrolisthesis at the involved level(s). The system spacers are intended to be used with autograft and/or allograft bone (comprised of cancellous and/or corticocancellous bone graft) or a bone void filler as cleared by FDA for use in intervertebral body fusion to facilitate fusion.

The Curiteva Porous PEEK Standalone ALIF spacer is an interbody fusion device to be used with three titanium alloy screws or anchors. When used with screws, the system is a standalone interbody fusion device. When used with anchors, the system is intended for use with supplemental fixation (e.g. facet screws or posterior fixation). Hyperlordotic implants (>20° lordosis) are intended for use with supplemental fixation (e.g. facet screws or posterior fixation).

Curiteva Porous PEEK ALIF System (Without Integrated Fixation)

The Curiteva Porous PEEK ALIF devices are intended for use 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. The system spacers are intended to be used with autograft and/or allograft bone (comprised of cancellous and/or corticocancellous bone graft) or a bone void filler as cleared by FDA for use in intervertebral body fusion to facilitate fusion. 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.

Please select the types of uses (select one or both, as applicable).	☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

510(k) Summary

Device Trade Name:	Curiteva Porous PEEK Standalone ALIF System
Manufacturer:	Curiteva, Inc. 25127 Will McComb Drive Tanner, AL 35671 Phone: (256) 213-1057 Fax: (256) 213-1058
Contact:	Eric Linder Chief Technology Officer regulatory@curiteva.com
Date Prepared:	June 4, 2025
Classifications:	21 CFR 888.3080 Intervertebral Fusion Device With Integrated Fixation, Lumbar
Class:	II
Product Codes:	OVD, MAX, PHM
Primary Predicate Device:	Globus Medical Inc. INDEPENDENCE® MIS Spacers (K160597)
Additional Predicate Devices:	Osseus Fusion Systems PISCES™-SA Standalone ALIF Interbody System (K213935) Curiteva Porous PEEK Lumbar Interbody Fusion System (K233744)

Indications For Use:

Curiteva Porous PEEK ALIF System (Without Integrated Fixation)

The Curiteva Porous PEEK Standalone ALIF devices are 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 I spondylolisthesis or retrolisthesis at the involved level(s). The system spacers are intended to be used with autograft and/or allograft bone (comprised of cancellous and/or corticocancellous bone graft) or a bone void filler as cleared by FDA for use in intervertebral body fusion to facilitate fusion.

The Curiteva Porous PEEK Standalone ALIF spacer is an interbody fusion device to be used with three titanium alloy screws or anchors. When used with screws, the system is a standalone

interbody fusion device. When used with anchors, the system is intended for use with supplemental fixation (e.g. facet screws or posterior fixation). Hyperlordotic implants (>20° lordosis) are intended for use with supplemental fixation (e.g. facet screws or posterior fixation).

Curiteva Porous PEEK ALIF System (Without Integrated Fixation)

The Curiteva Porous PEEK ALIF devices are intended for use 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. The system spacers are intended to be used with autograft and/or allograft bone (comprised of cancellous and/or corticocancellous bone graft) or a bone void filler as cleared by FDA for use in intervertebral body fusion to facilitate fusion. 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.

Device Description:

The Curiteva Porous PEEK Standalone ALIF System implants are provided sterile or non-sterile, are single-use devices, and available in a variety of different footprints, styles and sizes to accommodate the individual pathology and anatomical conditions of the patient. The subject system consists of interbody spacer implants that are generally box-shaped with an open central corridor to permit packing with autograft and/or allograft bone (comprised of cancellous and/or corticocancellous bone graft) or a bone void filler as cleared by FDA for use in intervertebral body fusion to facilitate fusion. The system also provides screws and anchors that can be inserted through the anterior portion of the spacers into adjacent vertebral bodies for bony fixation.

The Curiteva Porous PEEK Standalone ALIF System implants are manufactured from implant-grade PEEK (per ASTM F2026), Titanium alloy (per ASTM F136), and Tantalum (per ASTM F560). All Porous PEEK interbody spacers are additionally surface treated with a hydroxyapatite (HA) coating that is approximately 20nm thick.

Predicate Devices:

Curiteva, Inc. submits the following information in this Premarket Notification to demonstrate that, for the purposes of FDA's regulation of medical devices, the Curiteva Porous PEEK Standalone ALIF System is substantially equivalent in indications, design principles, and performance to the following predicate devices, which have been determined by FDA to be substantially equivalent to pre-amendment devices:

Primary Predicate Device:	Globus Medical Inc. INDEPENDENCE® MIS Spacers (K160597)
Additional Predicate Devices:	Osseus Fusion Systems PISCES™-SA Standalone ALIF Interbody System (K213935)
	Curiteva Porous PEEK Lumbar Interbody Fusion System (K233744)

Performance Testing Summary:

Non-clinical testing performed on the subject Curiteva Porous PEEK Standalone ALIF System supports substantial equivalence to predicate devices. The following testing was performed:

- Static and dynamic axial compression per ASTM F2077
- Static and dynamic compression-shear per ASTM F2077
- Subsidence per ASTM F2267
- Expulsion
- Particle characterization per ASTM F1877

The results of non-clinical testing demonstrate that the strength and performance of the Curiteva Porous PEEK Standalone ALIF System is sufficient for its intended use and is substantially equivalent to legally marketed predicate devices. A clinical literature justification was provided to support indications for use with bone void fillers.

Substantial Equivalence:

The subject Curiteva Porous PEEK Standalone ALIF System is substantially equivalent to legally marketed predicate devices cleared by the FDA. The subject device was shown to be substantially equivalent and to have similar technological characteristics to its predicate devices through comparison in areas including design, intended use, material composition, function, and range of sizes.

Conclusion:

The subject device and the predicate devices have the same intended use, have similar technological characteristics, and are made of similar materials. The subject and predicate devices are packaged in similar materials and are sterilized using similar methods. The data included in this submission demonstrate substantial equivalence to the predicate devices listed above. The Curiteva Porous PEEK Standalone ALIF System is as safe, as effective, and performs as well as, or better, than the predicate devices.