January 16, 2026

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

Re: K252205
Trade/Device Name: Curiteva Porous PEEK Cervical Interbody System; Curiteva Porous PEEK Lumbar Interbody System; Curiteva Porous PEEK Laminoplasty System; Curiteva Porous PEEK Standalone ALIF System
Regulation Number: 21 CFR 888.3080
Regulation Name: Intervertebral Body Fusion Device
Regulatory Class: Class II
Product Code: ODP, MAX, OVD, NQW, PHM
Dated: December 17, 2025
Received: December 17, 2025

Dear Eric 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

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K252205

Device Name
Curiteva Porous PEEK Cervical Interbody System, Curiteva Porous PEEK Lumbar Interbody System, Curiteva Porous PEEK Laminoplasty System, Curiteva Porous PEEK Standalone ALIF System

Indications for Use *(Describe)*

Curiteva Porous PEEK Cervical Interbody System

The Curiteva Porous PEEK Cervical Interbody Fusion System is indicated for intervertebral body fusion of the spine in skeletally mature patients. The Curiteva Porous PEEK Cervical Interbody Fusion System is intended for use for anterior cervical interbody fusion in patients with cervical disc degeneration and/or cervical spinal instability, as confirmed by imaging studies (radiographs, CT, MRI), that results in radiculopathy, myelopathy, and/or pain at multiple contiguous levels from C2 - T1. The Curiteva Porous PEEK Cervical Interbody Fusion System is intended to be used with supplemental fixation. The Curiteva Porous PEEK Cervical Interbody Fusion System is designed for use with autogenous and/or allogeneic bone graft comprised of cancellous and/or corticocancellous bone graft to facilitate fusion.

Curiteva Porous PEEK Lumbar Interbody System

The Curiteva Porous PEEK Lumbar lnterbody Fusion System is indicated for use in skeletally mature patients with degenerative disc disease (DDD) at one or two contiguous levels from L2 - S1. DDD is defined as back pain of discogenic origin with degeneration of the disc confirmed by patient history and radiographic studies. These DDD patients may also have up to Grade I spondylolisthesis or retrolisthesis at the involved level(s). Implants 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 and supplemental spinal fixation systems that have been cleared for use in the lumbar spine. Patients should receive at least six (6) months of non-operative treatment prior to treatment with the device.

Curiteva Porous PEEK Laminoplasty System

The Curiteva Porous PEEK Laminoplasty System is intended for use in the lower cervical and upper thoracic spine (C3 to T3) in laminoplasty procedures. The Curiteva Porous PEEK Laminoplasty System is used to hold or buttress the allograft or autograft material in place in order to prevent the graft material from expulsion or impinging the spinal cord.

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.

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.

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510(k) Summary

A. Submitter Information

Submitter:	Curiteva, Inc. 25127 Will McComb Drive Tanner, AL 35671 Phone: (256) 213-1057 Fax: (256) 213-1058
Contact Person:	Eric Linder regulatory@curiteva.com
Date Prepared:	January 16th, 2025

B. Device Information

Trade Name:	Curiteva Porous PEEK Cervical Interbody System Curiteva Porous PEEK Lumbar Interbody System Curiteva Porous PEEK Laminoplasty System Curiteva Porous PEEK Standalone ALIF System
Regulation Number:	21 CFR 888.3080, 21 CFR 888.3050
Regulatory Class:	Class II
Product Code(s) & Classification Name:	Curiteva Porous PEEK Cervical Interbody System ODP – Intervertebral fusion Device with Bone Graft, Cervical (21 CFR Part §888.3080) Curiteva Porous PEEK Lumbar Interbody System MAX – Intervertebral Fusion Device with Bone Graft, Lumbar (21 CFR Part §888.3080) Curiteva Porous PEEK Laminoplasty System NQW – Spinal Interlaminal Fixation Orthosis (21 CFR Part §888.3050) Curiteva Porous PEEK Standalone ALIF System OVD – Intervertebral Fusion Device with Integrated Fixation, Lumbar (21 CFR Part §888.3080) MAX – Intervertebral Fusion Device with Bone Graft, Lumbar (21 CFR Part §888.3080) PHM – Intervertebral Fusion Device with Bone Graft, Lumbar (21 CFR Part §888.3080)

Classification Panel:	Division of Orthopedic Devices
Predicate Device(s):	Curiteva Porous PEEK Cervical Interbody System (K213030) Curiteva Porous PEEK Lumbar Interbody System (K233744) Curiteva Porous PEEK Laminoplasty System (K243137) Curiteva Porous PEEK Standalone ALIF System (K250845)

C. Device Description

The previously cleared devices consist of a variety of interbody implants and spacers to provide support in the cervical, thoracic, lumbar, and/or lumbosacral regions of the spine. The system implants feature a proprietary nanomaterial surface treatment. This nanoscale surface texture is engineered to produce a uniform nanocrystalline hydroxyapatite layer approximately 10 – 20 nm thick, with individual crystals averaging 91.5 nm in length, and an average width of 10 nm.

The surface has demonstrated the ability to reduce contact angle (i.e., increase hydrophilicity) as compared to uncoated and micro-sized HA coated control surfaces and demonstrates elements to be considered a nanotechnology as outlined in the FDA nanotechnology guidance document.

D. Indications for Use

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Curiteva Porous PEEK Lumbar Interbody System
The Curiteva Porous PEEK Lumbar lnterbody Fusion System is indicated for use in skeletally mature patients with degenerative disc disease (DDD) at one or two contiguous levels from L2 - S1. DDD is defined as back pain of discogenic origin with degeneration of the disc confirmed by patient history and radiographic studies. These DDD patients may also have up to Grade I spondylolisthesis or retrolisthesis at the involved level(s). Implants 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 and supplemental spinal fixation systems that have been cleared for use in the lumbar spine. Patients should receive at least six (6) months of non-operative treatment prior to treatment with the device.

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Curiteva Porous PEEK Standalone ALIF System

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E. Comparison of Technological Characteristics

The technological design features of the subject implants were compared to the predicates in intended use, indications for use, design, function and technology and it was demonstrated that they are substantially equivalent.

F. Performance Data

In consideration of the FDA's Guidance for Industry: Considering Whether an FDA-Regulated Product Involves the Application of Nanotechnology, in vitro study results demonstrate that the nanoscale features of the Curiteva Porous PEEK System implants are uniformly present on the implant surface and exhibit enhanced hydrophilicity.

G. Conclusion

Based on the indications for use, technological characteristics, non-clinical performance testing, and comparison to predicate devices, the subject devices have shown to be substantially equivalent to legally marketed predicate devices.