January 18, 2024

Curiteva, Inc.
% Mr. Justin Eggleton
Vice President, Head of Musculoskeletal Regulatory Affairs
MCRA, LLC
803 7th Street NW
Washington, District of Columbia 20001

Re: K233744
Trade/Device Name: Curiteva Porous PEEK Lumbar Interbody Fusion System
Regulation Number: 21 CFR 888.3080
Regulation Name: Intervertebral Body Fusion Device
Regulatory Class: Class II
Product Code: MAX
Dated: November 21, 2023
Received: November 22, 2023

Dear Mr. Eggleton:

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.

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

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)*
K233744

Device Name
Curiteva Porous PEEK Lumbar Interbody Fusion System

Indications for Use *(Describe)*
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.

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.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

510(k) Summary

Device Trade Name:	Curiteva Porous PEEK Lumbar Interbody Fusion System
Manufacturer:	Curiteva, Inc. 25127 Will McComb Drive, Suite 100 Tanner, AL 35671 Phone: (256) 213-1057 Fax: (256) 213-1058
Contact:	Eric Linder Chief Technology Officer
Prepared by:	MCRA, LLC 803 7th Street, NW, 3rd Floor Washington, DC 20001 Office: 202.552.5800
Date Prepared:	November 21, 2023
Classifications:	21 CFR 888.3080 Intervertebral Fusion Device With Bone Graft, Lumbar
Class:	II
Product Codes:	MAX
Primary Predicate:	Curiteva Lumbar Interbody Fusion System – K181589
Reference Devices:	DePuy Spine CONDUIT™ Cages System – K222276 Curiteva Porous PEEK Cervical Interbody Fusion System – K213030

Indications For Use:
The Curiteva Porous PEEK Lumbar Interbody 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.

Device Description:
The Curiteva Porous PEEK Lumbar Interbody Fusion System implants are sterile, 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 implants are generally rectangle-shaped with an open central corridor to permit packing with bone graft to facilitate fusion. The implants have a dense outer ring with a porous structure lining the central graft corridor. The lateral sides of the implant may contain additional porous structures to allow for improved vascularization of the graft site to aid in fusion.

The Curiteva Porous PEEK Lumbar Interbody Fusion System implants are manufactured from implant-grade PEEK (per ASTM F2026) with Titanium alloy markers (per ASTM F136). Each implant has been surface treated with a hydroxyapatite (HA) coating that is approximately 20nm thick.

Predicate Device:
Curiteva, Inc submits the following information in this Premarket Notification to demonstrate that, for the purposes of FDA's regulation of medical devices, Curiteva Porous PEEK Lumbar Interbody Fusion 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:	Curiteva Lumbar Interbody Fusion System – K181589
Reference Devices:	DePuy Spine CONDUIT™ Cages System – K222276
	Curiteva Porous PEEK Cervical Interbody Fusion System – K213030

Performance Testing Summary:
Non-clinical testing performed on the subject Curiteva Porous PEEK Lumbar Interbody Fusion 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 Lumbar Interbody Fusion 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 Lumbar Interbody Fusion 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. Curiteva Porous PEEK Lumbar Interbody Fusion System is as safe, as effective, and performs as well as, or better, than the predicate devices.