October 28, 2024

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

Re: K243137
Trade/Device Name: Curiteva Porous PEEK Laminoplasty System
Regulation Number: 21 CFR 888.3050
Regulation Name: Spinal Interlaminal Fixation Orthosis
Regulatory Class: Class II
Product Code: NQW
Dated: September 30, 2024
Received: September 30, 2024

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,

Ethan R. Naylor -S

for Ronald P. Jean, Ph.D.
Director
DHT6B: Division of Spinal Devices
OHT6: Office of Orthopedic Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological

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)*
K243137

Device Name
Curiteva Porous PEEK Laminoplasty System

Indications for Use *(Describe)*
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.

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

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:	September 30th, 2024

B. Device Information

Trade Name:	Curiteva Porous PEEK Laminoplasty System
Common Name:	Spinal Interlaminal Fixation Orthosis
Classification Name:	Orthrosis, Spine, Plate, Laminoplasty, Metal
Device Classification:	Class II (per 21 CFR 888.3050)
Product Code:	NQW
Classification Panel:	Division of Orthopedic Devices
Predicate Device(s):	Primary: Curiteva Laminoplasty System (K231232) Reference: Curiteva Porous PEEK Cervical Interbody Fusion System (K213030)

C. Device Description

The Curiteva Porous PEEK Laminoplasty System is an internal fixation device for spinal surgery that consists of various configurations of plates and screws. The implant configurations are available in different types and sizes so that adaptations can be made to take into account pathology and individual patient anatomy. The plates come preformed with holes to receive bone screws. Screws are used to attach the plates to bone. System plate configurations may be used with allograft or autograft material. A hinge plate is provided when additional stabilization is necessary.

All system components are manufactured from Titanium alloy (Ti-6Al-4V ELI) that conforms to ASTM F136, or PEEK (Polyetheretherketone) as described by ASTM F2026.

The Curiteva Porous PEEK Laminoplasty implants are sterile, single-use devices and available in a variety of different sizes to accommodate the individual pathology and anatomical conditions of the patient. The implants have solid and porous PEEK regions.

The Curiteva Porous PEEK Laminoplasty implants are manufactured from implant-grade PEEK (per ASTM F2026). Each porous PEEK implant has been surface treated with a hydroxyapatite (HA) coating that is approximately 20nm thick.

D. Indications for Use

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.

E. Comparison of Technological Characteristics

As was established in this submission, the subject Curiteva Porous PEEK Laminoplasty System is substantially equivalent to other predicate devices cleared by the FDA for commercial distribution in the United States. 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.

F. Performance Data

Performance data is not included in this submission. The design changes being included for review do not present a new worst-case configuration that would require additional performance testing.

G. Conclusion

Based on the indications for use, technological characteristics, non-clinical performance testing, and comparison to predicate devices, the subject Curiteva Porous PEEK Laminoplasty System has been shown to be substantially equivalent to legally marketed predicate devices.