February 13, 2023

Curiteva, Inc.
% Meredith May, MS, RAC
Director of Consulting
Empirical Testing Corp.
4628 Northpark Drive
Colorado Springs, Colorado 80918

Re: K213030
Trade/Device Name: Curiteva Porous PEEK Cervical Interbody Fusion System
Regulation Number: 21 CFR 888.3080
Regulation Name: Intervertebral Body Fusion Device
Regulatory Class: Class II
Product Code: ODP
Dated: January 11, 2023
Received: January 11, 2023

Dear Ms. May:

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)*
K213030

Device Name
Curiteva Porous PEEK Cervical Interbody Fusion System

Indications for Use *(Describe)*
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 System is intended to be used with supplemental fixation. The System is designed for use with autogenous and/or allogeneic bone graft comprised of cancellous and/or corticocancellous bone graft to facilitate fusion.

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 – K213030

A. Submitter Information

Submitter:	Curiteva, Inc. 25127 Will McComb Drive, Suite 100 Tanner, AL 35671 Phone: (256) 213-1057 Fax: (256) 213-1058
Submitter Contact:	Eric Linder Chief Technology Officer
Regulatory Contact:	Meredith May MS, RAC Empirical Testing Corp. Phone: (719) 337-7579 mpvanderbilt@empiricaltech.com
Date Prepared:	February 9, 2023

B. Device Information

Trade Name:	Curiteva Porous PEEK Cervical Interbody Fusion System
Common Name:	Intervertebral Body Fusion Device
Classification Name:	Intervertebral Fusion Device With Bone Graft, Cervical
Device Classification:	Class II (per 21 CFR 888.3080)
Product Code:	ODP
Classification Panel:	Division of Orthopedic Devices
Predicate Device(s):	Primary: Curiteva Cervical Interbody Fusion System – K181261 Additional: Astura Medical ALTA Anterior Cervical Interbody Spacer – K173324 Additional: Cutting Edge Spine, LLC EVOL SI Joint Fusion System – K190025

C. Device Description

The Curiteva Porous PEEK Cervical 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 box-shaped with an open central corridor to permit packing with bone graft to facilitate fusion. The implants have a dense central ring with a porous structure lining the vertical graft corridor and on

the superior and inferior surfaces of the construct. Each implant has been surface treated with a hydroxyapatite (HA) coating that is approximately 20nm thick.

The Curiteva Porous PEEK Cervical Interbody Fusion System implants are manufactured from implant-grade PEEK (per ASTM F2026) with Titanium alloy markers (per ASTM F136).

D. Indications for Use

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 System is intended to be used with supplemental fixation. The System is designed for use with autogenous and/or allogeneic bone graft comprised of cancellous and/or corticocancellous bone graft to facilitate fusion.

E. Comparison of Technological Characteristics

As was established in this submission, the subject Curiteva Porous PEEK Cervical Interbody Fusion 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

Non-clinical testing performed on the Curiteva Porous PEEK Cervical Interbody Fusion System supports substantial equivalence to predicate devices. The following testing was performed:

- Axial compression per ASTM F2077
- Compression-shear per ASTM F2077
- Torsion per ASTM F2077
- Subsidence per ASTM F2267
- Wear debris characterization per ASTM F1877

Additional testing (e.g. expulsion, impaction) was performed to further support substantial equivalence. The results of non-clinical testing demonstrate that the strength and performance of the Curiteva Porous PEEK Cervical Interbody Fusion System is sufficient for its intended use and is substantially equivalent to legally marketed predicate devices.

G. Conclusion

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