August 28, 2019

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

Re: K191810
Trade/Device Name: Curiteva Pedicle Screw System
Regulation Number: 21 CFR 888.3070
Regulation Name: Thoracolumbosacral pedicle screw system
Regulatory Class: Class II
Product Code: NKB, KWP
Dated: July 3, 2019
Received: July 5, 2019

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 (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,

Ronald P. Jean -S

Ronald P. Jean, 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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K191810

Device Name
Curiteva Pedicle Screw System

Indications for Use *(Describe)*
The Curiteva Pedicle Screw System is intended for posterior, non-cervical pedicle screw fixation (T1-S2/ilium) and hook fixation (T1-L5) in skeletally mature patients as an adjunct to fusion for all of the following indications: degenerative disc disease (defined as discogenic back pain with degeneration of the disc confirmed by history and radiographic studies), spondylolisthesis, trauma (i.e., fracture or dislocation), deformities or curvatures (i.e. scoliosis, kyphosis, and/or lordosis), tumor, stenosis, pseudarthrosis and/or failed previous fusion. The Curiteva Pedicle Screw System is intended to be used with autograft and/or allograft.

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:	August 27, 2019

B. Device Information

Trade Name:	Curiteva Pedicle Screw System
Common Name:	Pedicle Screw System
Classification Name:	Thoracolumbosacral Pedicle Screw System
Device Classification:	Class II (per 21 CFR 888.3070)
Product Code(s):	NKB, KWP
Classification Panel:	Division of Orthopedic Devices
Predicate Device(s):	Zimmer Spine Vitality Spinal Fixation System – K150896
Additional predicate:	Clariance Spine Erisma LP MIS – K162367

C. Device Description

The Curiteva Pedicle Screw System is a thoracolumbar and/or sacral spine fixation system for spinal surgery that consists of a variety of screws, rods, set screws, crosslink connectors, rod connectors, and hooks. These implants are available in different sizes so that adaptations can be made to take into account pathology and individual patient anatomy.

The Curiteva Pedicle Screw System implants are manufactured from Titanium alloy (Ti-6Al-4V) that conforms to ASTM F136. Select rods are also available in medical grade Cobalt Chromium alloy (per ASTM F1537). All implants are intended for single use only and should not be reused under any circumstances.

D. Indications for Use

The Curiteva Pedicle Screw System is intended for posterior, non-cervical pedicle screw fixation (T1-S2/ilium) and hook fixation (T1-L5) in skeletally mature patients as an adjunct to fusion for all of the following indications: degenerative disc disease (defined as discogenic back pain with degeneration of the disc confirmed by history and radiographic studies), spondylolisthesis, trauma (i.e., fracture or dislocation), deformities or curvatures (i.e. scoliosis, kyphosis, and/or lordosis), tumor, stenosis, pseudarthrosis and/or failed previous fusion. The Curiteva Pedicle Screw System is intended to be used with autograft and/or allograft.

E. Technological Characteristics

As was established in this submission, the subject Curiteva Pedicle Screw 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 the same technological characteristics to its predicate devices through comparison in areas including design, intended use, material composition, function, and range of sizes.

F. Performance Data

The Curiteva Pedicle Screw System was mechanically tested in the following test modes: static and dynamic axial compression bend per ASTM F1717 and static torsion per ASTM F1717.

The results of this non-clinical testing show that the strength and performance of the Curiteva Pedicle Screw 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, performance testing, and comparison to predicate devices, the subject Curiteva Pedicle Screw System has been shown to be substantially equivalent to legally marketed predicate devices.